THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

In the Matter of Arbitration Between: APOTEX HOLDINGS INC. and APOTEX INC., Claimants, and THE UNITED STATES OF AMERICA, Respondent.	Case No. ARB(AF)12/1 (Revised) Volume 2

HEARING ON JURISDICTION AND THE MERITS

Tuesday, November 19, 2013

The World Bank
1225 Connecticut Avenue, N.W.
C Building
Conference Room C8-150
Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 9:00 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

MS. DAWN K. LARSON
Registered Diplomate Reporter
Realtime Reporter
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APPEARANCES:

Attending on behalf of the Claimants:

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Claimant's Representative:

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President and Chief Operating Officer
Apotex Inc.

MS. ROBERTA LOOMAR
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APPEARANCES: (Continued)

Attending on behalf of the Respondent:

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C O N T E N T S

CONFIDENTIAL PORTIONS

P R O C E E D I N G S

PRESIDENT VEEDER: Good morning, ladies and gentlemen. We'll start the second day of this hearing, Tuesday, the 19th of November.

Before we start, I'm going to ask the Secretary to the Tribunal to read out the times for yesterday, please.

SECRETARY TAYLOR: For housekeeping and procedural matters, this time was allocated to the Tribunal, and the time was 39 minutes and 49 seconds.

For the Opening Statement, the Claimants took 13 minutes and 55 seconds. For the Respondent, Opening Statement was 28 minutes, 12 seconds.

And for the Claimants' Case-in-Chief, it was 4 hours even and 19 seconds, and 21 minutes and 21 seconds for the Tribunal's questions of the Claimants during the presentation of the Case-in-Chief.

The total for November 18, 2013, Day 1, for the Claimants was 4 hours, 14 minutes, and 14 seconds; for the Respondent, 28 minutes, 12 seconds; for the Tribunal, 1 hour, 1 minute, 2 seconds; and the total was 5 hours, 43 minutes, 28 seconds. And I confirm

09:02:43 that those times were circulated to the Parties and the Tribunal last night by e-mail.

PRESIDENT VEEDER: Thank you for that. If there's any dispute about that, in particular the seconds, please let us know. Otherwise, we'll take it as agreed. We'll do this every day just to make sure we keep track of time. But please bear in mind that even, yesterday starting at 9:00, we didn't do six hours.

Any housekeeping? We ask that first of the Claimants.

MR. LEGUM: No, Mr. President.

PRESIDENT VEEDER: And of the Respondent?

MS. GROSH: No, Mr. President.

PRESIDENT VEEDER: Thank you. We will continue with the Claimants' case, Claimants' Witness.

MR. HAY: Yes. The Claimants call Sheldon Bradshaw.

SHELDON BRADSHAW, CLAIMANTS' WITNESS, CALLED

PRESIDENT VEEDER: Good morning, sir. You will see a form of words before you, an Expert Declaration.

09:03:37 We ask you to state your full name, and then if you're willing to do so, to read out the words of the Declaration.

THE WITNESS: I, Sheldon Taylor Bradshaw, solemnly declare upon my honor and conscience that my statement will be in accordance with my sincere belief.

PRESIDENT VEEDER: Thank you very much. There will now be questions from the Claimant.

DIRECT EXAMINATION

BY MR. HAY:

Q. Good morning, Mr. Bradshaw. Have you been retained by the Claimants to provide Expert testimony in this matter?

A. I was.

Q. As part of that engagement, have you prepared two Reports in this matter?

A. I did.

Q. Are copies of those Reports in front of you?

A. They are.

Q. Did you have any assistance in preparing those Reports?

A. I prepared them with Ron Johnson.
Q. Are there any changes or corrections that you'd like to make in your Report?
A. I would make one just quick correction to the Second Report. I think it's Paragraph 56. I note that the--there's a 4-year period after the FDA first discovered significance in cGMP violations at Paonta Sahib, and that actually should have been 2 1/2 years rather than 4 years. The inspection was in February of 2006, and the Import Alert was in September of 2008, so that would be 2 1/2 years rather than 4 years.
Q. Any other corrections?
A. No.
Q. Okay. Can you briefly summarize for the Tribunal the conclusions you reached in your Reports?
A. I think there was five main points that I would raise today in an effort to quickly summarize the two Reports.
I think the first key point is that the FDA's good manufacturing regulations apply to both companies manufacturing drug products in the United States and

companies manufacturing drug products abroad, and they apply in identical fashion.
I would further note that other statutory requirements and regulatory requirements apply equally to companies regardless of where they're manufacturing their products. The new drug approval process, post-approval requirements related to labeling changes, the submission of FARs, the submission of Adverse Event Reports, the submission of annual reports, important provisions like the definition of "adulteration." All of these statutory provisions and regulatory provisions apply the same to a company that's manufacturing drug products in the United States, and they apply in identical form to companies manufacturing drug products abroad for marketing in the United States.
I think the second key point that I would raise is that--is that FDA's enforcement tools are essentially the same as well. It doesn't matter whether a drug manufacturer is based in the United States or abroad, if they run afoul of FDA regulations--including FDA's Current Good

Manufacturing Practice regulations--the FDA can send either company a Warning Letter. The FDA can move to seize product from either company. It doesn't matter if a company is abroad. If they're marketing adulterated products in the United States, the FDA has the authority to seize those products.
Similarly, the FDA has the authority to seek an injunction against a foreign manufacturer, just as it would a domestic manufacturer, if that foreign manufacturer is, again, distributing products in the United States that the FDA concludes are misbranded or adulterated or otherwise not in compliance with the Food, Drug, and Cosmetic Act.
So these are enforcement tools are identical and could be applied to a company regardless of whether or not it's manufacturing in the United States or manufacturing outside the United States.
The primary difference is that the FDA has an administrative tool that allows them to stop products at the border and to detain them under a standard that the products appear to be adulterated or appear to be in violation of the Food, Drug, and Cosmetic Act.

In contrast, to detain product in the United States, that would require a judicial process whereby the FDA would be required to show that the product actually is adulterated. But, although there's this difference between this administrative tool and the judicial tool for domestic companies, the results can be the same. The FDA has the ability to stop a foreign company from manufacturing or distributing products in the United States through an Import Alert, but it has the exact same authority to prevent a U.S. company from distributing products through an injunction. So the tools might be slightly different, but the results can be precisely the same.
And I would further note that, with respect to this authority the FDA has at the border where it can detain products under a different standard, it may do that. And this is important--it may do that, but it's not required to do so. It's not required to detain products based on a lower standard. And like I said earlier, the FDA is free to seek an injunction or some other remedy against a foreign company if it believes its products are actually adulterated or

misbranded.

I think the third point I would make regarding the Report I co-authored is that by placing Apotex's Etobicoke and Signet facilities on the Import Alert, Apotex was treated less favorably than a number of U.S. and foreign companies under like circumstances. In my Report, I identify six companies that I believe to be in like circumstances with Apotex: Baxter, Perrigo, Hospira, Novartis/Sandoz, Teva, and Jelfa.

And I discuss in my Report the criteria that I looked at in considering whether a company was in like circumstances. I looked at companies that had--that were--had a similar business model to Apotex; were similar in size, were producing the same sorts of products, in this case pharmaceuticals. Companies--for the foreign companies, looked to see if they had an arm in the U.S. that was used to distribute those products, looked at whether or not companies received a Warning Letter during sort of the same time period raising the same sorts of issues. And I used those factors to sort of guide my thinking

in looking at companies that were similar to Apotex.

The fourth point I would make regarding my Reports would be that challenging--Apotex challenging its placement on the Import Alert would not have been a fruitful exercise. In this case, Apotex was added to an Import Alert based on an inspection that found they were not in compliance with FDA's Current Good Manufacturing Practices.

When a company is placed on Import Alert--in this case Import Alert 66-40--for failures to comply with FDA's Good Manufacturing Practices, the only way to come off such an Import Alert is to remediate the manufacturing deficiencies and then to be re-inspected by the FDA. And this case comports with my long understanding of how a company in those situations comes off an Import Alert because Apotex was told on several occasions by the FDA that the only way to come off the Import Alert was going to be through a re-inspection.

The final point I would make is that if the FDA had treated Apotex the same way it treats U.S. or domestic manufacturers who run afoul of the cGMP

regulations, Apotex would be allowed to continue shipping products into the United States and distributing them.

Typically, in a case involving cGMP violations, the FDA sends the domestic company a Warning Letter, but then it gives it a significant period of time to correct the violations, to get back into compliance, and typically during that time period the company is allowed to continue distributing drug products.

So had the United States treated Apotex the way it treats U.S. manufacturers, Apotex would not have been prevented from distributing products in the United States during that time period.

Q. Did you, as part of your engagement, review the Expert Report submitted in this matter by Mr. Vodra?

A. I did.

Q. Have you formed any opinions concerning the Statements and Opinions expressed by Mr. Vodra in his Report?

A. I have.

Q. Can you briefly summarize those for us?

A. Sure.

As an initial matter, I would say that I agreed with a significant portion of Mr. Vodra's Report. In large part, he sets forth what I would describe as general principles of FDA law with which I do not have any quarrel whatsoever. There are some instances where he draws inferences or makes conclusions based on some of those principles with which I disagree, and I might maybe raise a couple examples of where I would disagree with him right now.

For example, with respect to the risk of the Apotex drugs, I agree with him that the FDA is not required to make some finding of actual harm before it decides to take some action against a company who's out of compliance with good manufacturing practices, but I must admit I don't understand his conclusion where he determines that, in fact, a number of Apotex drugs actually posed an immediate risk to the public health.

He specifically mentions three drugs in his Report, but--for that proposition, but his concerns

09:16:00 with respect to those three drugs are at odds with what the FDA both said and did at the time. With respect to two of the drugs, they were placed--two of the three drugs were recalled, and the FDA classified those--the recall as Class II, which means that there--any risk, significant risk to the public health was remote. So the FDA's contemporaneous finding about two of the three drugs was that any risk to the public health, significant risk to the public health was remote.

With respect to the third drug, the FDA was aware of and looked at the very allegations that Mr. Vodra raises in his Report and didn't require any action be taken. So I must admit that I disagree and don't fully understand his conclusion or how he concluded that any of the Apotex drugs actually posed a risk to the public health.

The second area where I would have some disagreement is in his discussion of FDA's enforcement tools. He goes on to note that FDA's enforcement tools aren't symmetrical. And I acknowledge that the enforcement tools aren't necessarily symmetrical, but

09:17:25 what he doesn't go on to say, though, is that the FDA can achieve the exact same result for both domestic companies and foreign companies through the use of different tools. And so, yes, the FDA has some special tools that it can use at the border that obviously are only going to apply to foreign drug manufacturers, but if the FDA wants to stop a drug manufacturer from distributing product in the United States, it can do so either with an injunction for both domestic or a foreign company, or it can use an Import Alert for a foreign company.

So, it might have different tools to use, but it can achieve the exact same result. It can place in--a foreign drug manufacturer and a domestic drug manufacturer in the identical place, but just with the use of different tools.

The third area where I would take some exception with his Report is in his discussion of the discretion that the FDA has. I actually agree that the FDA has significant amount of discretion in the way it enforces the Food, Drug, and Cosmetic Act, but in his Report, he suggests that the FDA need not take

09:18:49 the same action against companies that are in like circumstances. And with that, I would disagree. If companies actually are in like circumstances, the law requires that the FDA not act arbitrarily and capriciously. And the classic example of arbitrary and capricious conduct is treating two Parties in the same circumstances differently.

And so the FDA does have to comply with the law, and it can't use the discretion it has in a way that would violate the law.

The fourth area where I have some disagreements with his Report is in the area of whether or not the--Apotex had any what he called "meaningful procedures" to be removed from the Import Alert. He offers several suggestions on ways in which one can challenge FDA action. And these are actions that I've invoked on behalf of my clients in various contexts but never in the context where you're trying to remove a company from an Import Alert when they've been placed on that Import Alert based on an FDA inspection finding cGMP violations.

In those cases, as the FDA again has

09:20:20 repeatedly said in this case, the only way to get off an Import Alert when you've been placed there because of an inspection finding cGMP violations is to correct the violations and to then be re-inspected by the Government.

And I think it's interesting that although the Report notes that there are these mechanisms where you can challenge FDA action, neither in his Report or in--and in nothing that I saw from the Government showed even one example of anyone ever getting off an Import Alert based on cGMP violations found during an FDA inspection through one of those mechanisms, and I'm not aware of anyone ever using any of those avenues to successfully get off an Import Alert.

That would be, I guess, my summary of his Report.

MR. HAY: Thank you. Claimant has no further questions of this Witness.

PRESIDENT VEEDER: Thank you very much. There will now be questions from the Respondent.

MR. BIGGE: Thank you, Mr. President.

CROSS-EXAMINATION

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BY MR. BIGGE:

Q. Mr. Bradshaw, my name is David Bigge. I represent the Respondent, the United States of America. We have a few questions for you just to clarify a few points in your Report.

First, I wanted to quickly--just so I'm clear--run through your background.

You graduated from law school in 1996; is that correct?

A. Correct.

Q. And then you clerked for a judge on the Fourth Circuit?

A. I did.

Q. Until 1999; is that correct?

A. Yes, for three years.

Q. And then you worked for the presidential campaign for George W. Bush?

A. I did not.

Q. Oh, you did not?

A. Yes.

Q. Okay. So your next job after your clerkship was the Department of Justice?

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A. No. It was at a law firm--that no longer exists--Howrey & Simon.

Q. Howrey & Simon.

Okay. Did you practice FDA law at Howrey & Simon?

A. I did not.

Q. And then after Howrey & Simon, you went to the Department of Justice--

A. I did.

Q. -- is that correct?

And you were in the Civil Rights Division at the Department of Justice?

A. I was--I started for three years at the Office of Legal Counsel at the U.S. Department of Justice.

Q. Okay. And then at some point did you do civil rights at the Department of Justice?

A. I did. In around 2004, perhaps--I believe it was 2003. Let's see. 2004, I moved to the Civil Rights Division.

Q. Okay. You mention in your Expert Report that you advised--in your capacity at the Department of Justice, you advised FDA on a few occasions.

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Were any of those occasions related to cGMP enforcement?

A. They were not.

Q. And you also mention in the your Expert Report that you provided testimony to Congress on two occasions related to FDA.

Were either of those related to cGMP enforcement?

A. They were not.

Q. In 2005, March of 2005, you became Chief Counsel at FDA; correct?

A. Correct.

Q. You had not served at FDA before this position?

A. I had not.

Q. And you stayed at FDA in the Chief Counsel's position until October of 2007?

A. I believe so, yeah.

Q. At which point you became a partner at Hunton & Williams?

A. Correct.

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Q. And you're now the head of that firm's FDA practice?

A. Yeah, I'm the co-chair.

Q. Okay. I'd like to start with something in your First Report. You noted in Paragraph 3 of your First Report that Health Canada found Apotex's facilities compliant in 2009. I'll give you a moment to look at it?

PRESIDENT VEEDER: Give me the paragraph number.

MR. BIGGE: Yes, I'm sorry. 33.

Actually, that doesn't appear to be correct. I apologize.

BY MR. BIGGE:

Q. Well, do you recall in your--

MR. BIGGE: I'm sorry, I'm looking at the Memorial. Give me just one minute.

PRESIDENT VEEDER: It looks like 33, Page 7.

MR. BIGGE: Yes. Yes.

BY MR. BIGGE:

Q. Do you see where you say, "As a result of Import Alert, Health Canada conducted its own

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09:24:50 extensive inspection of the Etobicoke and Signet facilities. Health Canada concluded that the two sites were cGMP compliant."

Do you see that?

A. I do.

Q. Okay. Were you aware that the exit inspection notice for the Signet facility listed 26--and this was issued by Health Canada--listed 26 separate cGMP observations?

A. Well, I understand that their--Health Canada--I understand that Health Canada came in and inspected and made a number of observations but did not find any deficiencies that warranted a halt on manufacturing at the facility or that would prevent distribution of drugs from that facility.

Q. But you agree with me that there were 26 separate cGMP observations in that Report?

A. I cannot remember the precise number, but there were observations.

Q. Do you recall that 18 of them were what Health Canada calls Risk 2 observations?

A. I couldn't tell you what the number were.

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09:25:53 Q. Do you recall seeing Risk 2 observations in that Report?

A. I remember that there were observations, but again, I couldn't tell you the number or how they were characterized beyond the fact that they weren't sufficient to have Health Canada either require that they stop manufacturing or distributing drug products.

Q. Would you disagree with me if I represented to you that a number of those observations were Risk 2 observations?

A. Obviously I don't have that document in front of me, so I have no way of challenging what you're saying.

Q. That's fair.

Assuming for the sake of argument that that document does include 18 Risk 2 observations, did you know that Health Canada has described multiple Risk 2 observations as indicating "the company does not control its processes and operations sufficiently"?

A. Again, I'm aware that Health Canada came in and made a number of observations, none of which led Health Canada to believe that either manufacturing of

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09:26:57 drugs or the distribution of drugs should be prevented.

Q. Also as a result of that inspection, were you aware that Health Canada imposed terms and conditions on Apotex in order to issue it its 2010 Establishment License?

A. No. I understand that there were things that Apotex was required to do to continue manufacturing, but again, the point was that Health Canada came in and didn't find anything that warranted their either being shut down or that prevented them from continuing to distribute drugs.

Q. Have you seen the terms and conditions? Did you review that document before you drafted your Report?

A. You know, I recall seeing documents from Health Canada. I don't know--again, I reviewed literally thousands of documents, so, if you have a copy--

Q. I do. And I'll get that to you.

MR. BIGGE: Abby, can we bring up Joint Bundle 58? We'll give you a paper copy as well.

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09:28:13 MR. HAY: Excuse me. Can you tell us the exhibit number?

MR. BIGGE: Yes; I'm sorry. That is C-126 and it is Exhibit 58 in the Joint Core Bundle.

BY MR. BIGGE:

Q. So these are the terms and conditions imposed by Health Canada.

Does seeing this document refresh your recollection of whether you reviewed it before you wrote your Report?

A. You know, it doesn't, although I haven't had a chances to read it yet, so.

Q. That's fine. Take your time.

A. Would you like me to do so?

Q. Sure.

PRESIDENT VEEDER: Before the Witness answers that question, this a confidential document. Do we need to cut the feed?

MR. SHARPE: Mr. President, if I might, almost all the fact documents have been designated confidential on both sides, partly to allow--to signal that there may be confidential information in the

documents to give the Parties time to go and redact any confidential information.

So we are working with Claimants to try to minimize any actual confidential information being put up on the slide. So just because a document is labeled "confidential" doesn't mean, from our perspective, that we need to cut the feed.

MR. HAY: Well, from our perspective, if you're going to start asking him questions about specific process issues and particular drugs, et cetera, we would want that portion of the feed cut off as confidential.

I don't know what you're going to ask him, so it's hard for me to anticipate that, but it sounds like we're approaching that. So our suggestion would be to cut the feed off at this point.

MR. SHARPE: From our perspective, we can't have the whole arbitration discussing Apotex's facts and information in the record be cut off from the public. This is a public proceeding.

PRESIDENT VEEDER: Equally, we can't have confidential information provided through the feed if

it's confidential. How are we going to do this? Obviously, it is more attractive to have an open system, but we don't know what the Witness is going to say by way of answer. Nobody does except him.

What do we do?

MR. SHARPE: Can we have just a moment?

PRESIDENT VEEDER: Let's take a few minutes.

If you don't mind just waiting right there while we sort this out.

THE WITNESS: That's fine.

(Pause.)

MR. BIGGE: Mr. President, so I understand, we will agree to cut off the feed for this portion. I only have a few more questions on this document, and I will alert the Tribunal when I'm done, and then we can restart the feed.

PRESIDENT VEEDER: Okay. Before we proceed--this may happen again with other documents.

MR. BIGGE: I'll be aware.

PRESIDENT VEEDER: Given that the Witness is effectively "in perda"--he can't talk, obviously, to counsel for the Claimant while he's giving evidence

except through questions in the face of Tribunal--would you be willing to provide a list of documents to which you're going to refer in your cross-examination in advance to the Claimants so they can start seeing in advance whether there is any difficulty or no difficulty in relation to your cross-examination?

MR. BIGGE: The difficulty is, Mr. President, that I don't have them in a list. I have them in an outline with my questions, which I obviously cannot hand over.

PRESIDENT VEEDER: Let's stop you there because you cross-examine the way I did. So I understand the problem. You haven't got a list.

MR. BIGGE: Thank you.

PRESIDENT VEEDER: Let's see how it goes. But maybe if we have a break, then we can look at this again and the list can be produced. Maybe that's the answer. If you had some advance notice of which documents were going to be--

MR. HAY: Absolutely, that would certainly be helpful.

PRESIDENT VEEDER: Because I take the point, we should not cut the feed when we don't need to cut the feed.

Well, for the moment, we'll cut feed, so I would ask the Secretary to confirm that the feed has been cut in relation to questions arising on this document.

SECRETARY TAYLOR: I can confirm that the feed has now been cut to the public hearing room.

CONFIDENTIAL PORTION

PRESIDENT VEEDER: Let's proceed.

BY MR. BIGGE:

Q. Okay. Mr. Bradshaw, you've now had ample opportunity look at the document.

Any recollection whether you reviewed this before you wrote in your Report that Health Canada found Apotex compliant?

A. It's not immediately jumping out to me that I reviewed this, but I reviewed a number of documents, including documents related to Health Canada.

Q. Okay. Looking that the document now, do you see that there were terms and conditions that Health CanadaHealth Canada imposed in order to issue Apotex an Establishment License in 2010?

A. Sure. And just way of clarification at the very beginning, I'm not an Expert on Health Canada, so it's not entirely clear to me, you know, the meaning of this document beyond sort of its--you know, what it purports to be.

But it doesn't necessarily purport on its face that these conditions are being required because

Health Canada believes them to be out of compliance with cGMP. Nowhere does it say that.

Q. Do you see the reference at the top of Page 2 that says "Pursuant to Section C.0(1)(a).008(4) of the food and drug regulations"?

A. I see that. But like I said, I'm not familiar with the Canadian regulatory regime, and I couldn't tell you what C.0(1)(a).008(4) says.

Q. Okay.

MR. BIGGE: Abby, could you bring up RLA-173? Oh, we can't bring them up because of the screen?

(Pause.)

BY MR. BIGGE:

Q. So, Mr. Bradshaw, I see you're turning to the section. You have to turn several pages to get to C.0(1)(a).008 and then Subpart (4) of that section, it's right above some charts.

Were you aware that under this Canada law it says, "The Minister may, in addition to the requirements of Subsection 2, set out an Establishment License, terms and conditions, respecting (a), the tests to be performed in respect of a drug and the

equipment to be used to ensure that the drug is not unsafe for use and, (b), any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged, labeled, or tested"?

Do you see that section?

A. I do.

Q. And do you agree that that is the same subsection that is referenced in the terms and conditions that were applied to Apotex by Health Canada in 2009?

A. It appears to be, yeah.

Q. Okay. You can put that document down. Thank you.

MR. BIGGE: We can reopen the feed. That ends this line of questioning.

NONCONFIDENTIAL PORTION

SECRETARY TAYLOR: Confirming that the feed is now back on to the public hearing room.

MR. BIGGE: I apologize for this, Mr. Taylor. I actually think we should cut the feed again. I'm looking now at my line of questioning and realizing that we're going to get back into the same problem.

PRESIDENT VEEDER: Well, with apologies for those watching, this is going to be awkward, but let's cut the feed again.

SECRETARY TAYLOR: Confirming that the feed has, again, been cut to the public hearing room.

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CONFIDENTIAL PORTION

BY MR. BIGGE:

Q. Mr. Bradshaw, if I could have you pick up your First Report and turn to Paragraph 154.

Are you there?

A. Yes.

Q. The last several lines of that paragraph read: "In light of Apotex's clean re-inspection, it is clear that FDA would not have taken any enforcement action against Apotex had its facilities been located in the United States."

That was the Opinion you referenced if your direct testimony; correct?

A. Give me a moment to review 154. I've read the sentence in question.

Q. Okay. So you agree with me, you mentioned on your direct testimony that it is your view that had Apotex been a U.S. facility, it would not have been put on the Import Alert. And in this paragraph, you base that--you start that sentence with "in light of Apotex's clean re-inspection in 2011."

Is that correct?

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A. I'm not sure I said the first half. If Apotex were in the U.S., they obviously wouldn't be on an Import Alert. I think what I said is if they treated Apotex the same as they treat U.S. companies that have similar cGMP violations, they would not obviously have prevented Apotex from distributing drug products because for domestic products that have similar cGMP problems, they're allowed to continue. They may receive a Warning Letter, but they're typically allowed to continue manufacturing and distributing drug products, and often given years if not longer to come back into compliance.

My point here is that had FDA applied the same sort of standards to Apotex that it applies to domestic companies, that it would have given them an opportunity to correct the problems, and based upon the subsequent re-inspection which ultimately resulted in the Import Alert being lifted, that based on that subsequent inspection, that would have--had they been treated as a domestic company, they would have been allowed to continue manufacturing, and then that would have been the end of the matter.

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Q. Okay. You said a couple things there I want to touch on.

First, you said "similar types of cGMP violations." You've based your analysis on these similar types of cGMP violations based on what you see in the different Warning Letters?

A. Well, one of the things that we did, rather than trying to delve into whether or not a cGMP violation was or was not significant, was just to treat them as the FDA characterized them. And that's the virtue of looking at companies that received Warning Letters because, by definition, a Warning Letter is only sent to a company where the issues are of significant--regulatorily significant.

And so by the FDA issuing a Warning Letter, the FDA itself has said: "These cGMP violations are significant."

So, I use the Warning Letters as a guide in helping sort of determine whether or not the FDA viewed a particular violations as being significant or not.

Q. Okay. Now, you also--you mention the

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ultimate re-inspection. I'd actually like you to look back at your Report again at Paragraph 164. And I will read this for the record as well.

You write, "In light of Apotex's clean re-inspection in 2011, it is clear that, had Apotex's facilities been located in the U.S., (a) FDA would have taken no enforcement action against Apotex until providing the company an opportunity to respond to inspectional observations and to implement corrective measures; and (b) FDA's investigation would actually have been closed out without any enforcement action ever being taken."

My question is, prior to making those statements in Paragraph 154 and 164, what documents did you review related to the 2011 inspection of Etobicoke and Signet?

A. I would have looked at documents related to those inspections, 483s and the like.

Q. EIRs? Sorry; the Establishment Inspection Reports?

A. Yes.

Q. So you were aware, then, that the Form 483

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for Signet for the 2011 re-inspection included 22 new or ongoing cGMP violations?

A. Again, it's been a while since I've looked at that. I know that there were observations, but again, the observations were not sufficient enough to either generate--to keep Apotex on the Import Alert. In fact, FDA found that the inspections to ultimately warrant Apotex being removed from the Import Alert. So, again, I'm relying on FDA's own characterization of the significance of those violations.

And based on what the FDA did in response to that re-inspection, it is clear that had that been a domestic company, that, again, the company would not have been prevented from manufacturing products or distributing them in the United States.

Q. But you are aware, or at least at one time you were aware, that there were a list of 22 new and ongoing deficiencies on the Form 483 for Signet in 2011?

A. Sure. But, again, the FDA's own treatment--

Q. I understand. I'm sorry.

If you could just answer the question. Were

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you aware or are you aware now that there were 22 observations on that Form 483?

A. Again, I'm not sure I could tell you right now that I knew there were 22, but I knew there were observations that were not considered serious.

Q. Were you aware that the investigators on that 2011 re-inspection concluded that: "The previous inspectional observations have not been fully corrected"?

A. I was aware that inspectors made observations regarding whether or not all of the previously identified issues had been fully remediated. But again, the conclusions I'm drawing about that are based on the FDA's treatment of that inspection.

Q. Were you aware that in the Etobicoke Establishment Inspection Report, the investigators wrote that their re-inspection "uncovered significant systemic and ongoing objectionable conditions. Corrective action has not been fully implemented to every objectionable condition cited in the 2008 inspection"?

A. Yes. I understand that the inspectors found

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that they had not remediated every single--fully remediated every single one of the prior observations, but again, my characterization of the inspection is based on how the FDA ultimately treated that and the steps they took as a result thereof.

Q. Now, I have a couple more questions--well, one last question on what is in those reports.

Were you aware that in the 2011 Signet Establishment Inspection Report the investigators noted that Dr. Jeremy Desai, Apotex's CEO, admitted that Apotex was "not meeting FDA's expectations"?

A. Again, I understand that the FDA noted that not every observation had been fully remediated.

Q. And you are aware that the investigators on that inspection recommended official action and recommended that Apotex remain on the Import Alert?

A. Yeah. I know that--I know that senior officials in FDA disagreed with that, with that position.

Q. Right. So, I want to run through a few of the facts leading up to this 2011 "clean re-inspection," as you described it.

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This inspection was approximately a year and a half after Apotex was put on the Import Alert; is that correct?

A. The re-inspection, I want to say, was in January.

Q. That's right.

A. Okay. Yes.

Q. Okay. So, if--this was in January of 2011. They were put on Import Alert in August of 2009; correct?

A. Yes.

Q. And that at the time, Apotex admitted that it had cGMP violations in 2009?

A. Well, I think the--it's my understanding the company was working with the FDA to remediate the observations that the FDA had previously found.

Q. Were you aware that Apotex [redacted] its head of quality assurance, a gentleman named Lance Lovelock?

A. I know that they made management changes in that area, yes.

Q. In 2009 and 2010?

A. I couldn't have given you the actual name of

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the person.
Q. Were you aware that Apotex hired scores or maybe even hundreds of additional quality assurance personnel between the time the Import Alert was imposed and the 2011 re-inspection?
A. I'm aware that they hired a number of individuals and retained third parties to help with the remediation efforts.
Q. Were you aware that Apotex claims to have spent [redacted] on cGMP remediation or told FDA that they had spent that money in March of 2010?
A. I'm aware that they spent [redacted]. I'm guessing that, if you look at all of the money that was spent, it would probably be even, I would imagine, significantly more than [redacted].
Q. And, in fact, although we can't be sure this is a correct number, Howard Rosen, who submitted an Expert Report in this case, claimed total remediation costs of around [redacted].
Were you aware of that?
A. Like I said, I would have guessed it would have been a lot more than [redacted]. I'm not sure I

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was aware of the [redacted] number.
Q. Were you aware that Apotex hired [redacted] different cGMP consultants to assist it in remediating its cGMP violations?
A. I was aware that it hired a number of third-party cGMP Experts to assist it.
Q. And that Apotex waited until August of 2010 to invite the FDA back to re-inspect the Etobicoke facility?
A. I'm not sure what you mean by "waited."
Q. Well, FDA received a notice from Apotex in August of 2010 requesting the re-inspection. Were you aware of that?
A. Yes. I understand that. I understand that that's at the time they felt that they were obviously prepared for a re-inspection.
Q. So it was a year between the Import Alert and their request for re-inspection in August of 2010; is that correct?
A. That's my understanding.
Q. And that they submitted a request for re-inspection of Signet in 2010?

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A. Approximately. It was roughly in that time period.
Q. And that it requested these re-inspections in October of 2010?
A. Well, the--
Q. Were you aware that in the August and September 2010 letters requesting re-inspection that the re-inspection was requested not immediately, but in October of 2010?
A. Well, I know that they were hoping to have inspectors in that time period, and I know that originally they were scheduled for around November of that time period. Then the FDA canceled and rescheduled for January of 2011.
Q. Correct. So, in fact, they had--between their request and the re-inspection, they had an additional five months to work on any cGMP problems they may have had?
A. Well, certainly there was an additional time period between the request for an inspection and the actual inspection.
Q. And in light of all that and what you

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describe as the "clean re-inspection," you conclude that FDA never would have put Apotex on the Import Alert in the first place?
A. Well, no. My position is that had they treated Apotex the same way they treat U.S. manufacturers, they would not have prevented Apotex from distributing product in the United States.
If you look at companies that were in like circumstances, they're allowed to go for years and years, often five years, with significantly more interaction with the FDA with respect to Warning Letters and the like without the FDA ever making any effort to stop them from distributing drug products.
Q. Now, when talking about those other companies and their significant cGMP violations, you mentioned that you relied on the Warning Letters--
MR. BIGGE: I'm sorry. And we--I think we can--
PRESIDENT VEEDER: I think we are in a position now to put back on the feed, aren't we?
MR. BIGGE: I was just about to suggest that. Thank you.

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PRESIDENT VEEDER: Thank you very much. I'll ask the Secretary to confirm it. Can I explain? We have to be guided by both sides. It's difficult for us to police this. We are not as sensitive as each of you are to the documentation.

MR. BIGGE: I do not anticipate that any of the remainder of my questions will involve any confidential information.

SECRETARY TAYLOR: I'm confirming that the feed has now been recommenced to the public hearing room.

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NONCONFIDENTIAL PORTION

BY MR. BIGGE:

Q. Now, you mentioned that you--you based your comparator analysis, you said in your affirmative presentation at the start of this morning that you based that presentation on your examination of warning letters. You just--you reaffirmed that during this cross-examination, so I wanted to talk a bit about Warning Letters.

Now, when you were Chief Counsel at FDA, wasn't it the case that all Warning Letters were reviewed by the Office of Chief Counsel, your office?

A. Yes. During the time period I was Chief Counsel, our office reviewed and cleared every Warning Letter issued by the Agency.

Q. But that was not the policy prior to 2001; correct?

A. Yes. It was 2001 when that policy was implemented. So prior to 2001, Warning Letters were not regularly reviewed by the Office of the Chief Counsel for legal sufficiency.

Q. But between 2001 and 2009, all Warning

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Letters were reviewed by your office, the Office of Chief Counsel; correct?

A. That's correct.

Q. And as you mentioned, the policy was instituted to ensure that the Warning Letters would support an enforcement action if one were necessary; correct?

A. Correct.

Q. And so your office checked the legal sufficiency, as you mentioned. Also they made sure that the factual assertions had some basis; correct?

A. Correct.

Q. But that policy was changed in August 2009; correct?

A. Correct.

Q. So after 2009, Warning Letters did not have to be checked by the Office of Chief Counsel?

A. That's correct.

Q. And haven't you publicly expressed the view that because there is no legal review, you don't have confidence that Warning Letters that were published after August of 2009 would necessarily support an

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enforcement action?

A. That's correct. I have concerns about some Warning Letters issued following that time period.

Q. I'd like you to turn to Paragraph 28 of your Second Report.

A. I'm sorry. Did you say "Page" or "Paragraph"?

Q. Paragraph. It's on Page 12. Okay. Everyone is with me. You--I'll read the paragraph in full for the record, but you identify the dates of the Warning Letters you looked at in this paragraph.

You wrote, "Like Apotex, each of the comparable businesses cited in the First Report received an FDA Warning Letter during the 2008-2011 time period that alleged violations of drug cGMPs. Baxter received a Warning Letter from FDA identifying 'significant Violations of Current Good Manufacturing Practice (cGMP) regulations for finished pharmaceuticals' on January 20, 2011. Perrigo received a Warning Letter from FDA alleging significant violations of drug cGMPs on April 29, 2010. Hospira received an FDA Warning Letter alleging

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significant cGMP violations on April 12, 2010. Novartis received an FDA Warning Letter related to deficiencies in Sandoz's manufacturing operations on November 18, 2011. Teva received two Warning Letters alleging significant cGMP violations, first on December 11, 2009, and second on January 31, 2011. And Jelfa received a Warning Letter alleging cGMP violations on July 14, 2011."

So all of those Warning Letters were after this change in policy at FDA; correct?

A. The ones cited here, correct.

MR. BIGGE: Could you give me just one moment. I only have a few more questions. I just want to take a moment to confer.

(Pause.)

BY MR. BIGGE:

Q. Just a few more questions.

First, you mentioned in your direct examination that when Apotex recalled its products, it only recalled them under Class II, which you said indicated to you that the risk of injury was remote.

I'd like to read to you the official agency

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standard for recall classification. It's in Mr. Vodra's Report at Paragraph 31.

The full Class II recall provision reads, "A situation in"--

PRESIDENT VEEDER: Wait for the Witness.

BY MR. BIGGE:

Q. It reads, "Class II recall: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."

Now, in your Report, you only cite to that second clause; correct?

A. I focus on that, in part, because the Government's case seems--or the Vodra Report seemed to focus on sort of the immediate and serious health consequences not being remote, but being very, very likely. So, that seemed to be the clause that was most relevant to the--or corresponding to the allegations that he was making about the products.

Q. But sitting here today, you don't know whether FDA designated Apotex's recall as

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Class II based on the "may cause temporary or medically reversible adverse health consequences" clause or the "where the probability of serious adverse health consequences is remote" clause.

Do you have any basis of knowing why FDA imposed a Class II recall?

A. Yeah. I can say this. If the probability of serious health consequences had not been remote, had the probability of serious adverse health consequences been likely, then that would be a Class I recall. So by making this a Class II recall, even if you would look at the first clause, you would not have a Class II recall if the risk was significant and likely.

Q. Just a few more questions.

Regarding your comparator, when it was put on the Warning Letter, Teva Parenteral, which was in Irvine, California, was producing only sterile injectables; isn't that correct?

A. Well, that's an injectable facility in Irvine.

Q. Okay. And it's the same for Hospira and

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Sandoz Canada; right? Those were both producing sterile injectable products?

A. Hospira has multiple facilities that have had problems; many of them, like the ones in Rocky Mount and Clayton, make injectables, but they've also had problems at facilities in Colorado, in Texas, in India.

Q. But the Warning Letter related to the two facilities you mentioned that made sterile injectables; correct?

A. The one in Rocky Mount.

Q. Right. And Sandoz Canada in Boucherville also does sterile injectables; correct?

A. I believe they make sterile injectables there.

Q. Now, in 2009, Apotex was not producing any injectable products at the Signet facility; correct?

A. Apotex?

Q. Yes. At the Signet facility?

A. That's my understanding.

Q. They were doing oral solid dosages?

A. That's my understanding.

Q. And in 2009, Apotex was not producing any injectable products at the Etobicoke facility; correct?
A. That's my understanding.
Q. Turning to some of your other comparators, Baxter's Puerto Rican facilities were producing liquid products; is that correct? They were not necessarily sterile, but they were liquid pharmaceutical products?
A. It's my understanding. I'm not sure I know precisely the entire product makeup of the Puerto Rican facilities.
Q. And Perrigo was producing both liquid products and some solid oral dosages; correct?
A. I believe so.
Q. But again, Apotex's Etobicoke and Signet facilities produced only oral solid dosages; correct?
A. That's my understanding.
Q. But Apotex does produce sterile injectables and liquid products at another Canadian facility; isn't that right?
A. That's my understanding.
Q. That's the Richmond Hill facility?

A. Correct.
Q. And it produces for the U.S. market nasal sprays and liquid ophthalmics?
A. That's my understanding.
Q. But Apotex's Richmond Hill facility was not put on the Import Alert in August of 2009; correct?
A. They were not.
Q. And that facility was inspected by FDA in 2010, were you aware of that?
A. I am aware that they were inspected.
Q. And they received a Form 483 for that Richmond Hill facility after that inspection listing several cGMP violations?
A. That's my understanding.
Q. But, again, that Richmond Hill facility was never added to the Import Alert; correct?
A. That's correct.
Q. Okay.
MR. BIGGE: We don't have any further questions. Thank you.
Thank you, Mr. Bradshaw.
PRESIDENT VEEDER: Thank you very much.

There will now be questions from the Claimant by way of reexamination.
MR. HAY: The Claimant has no redirect.
PRESIDENT VEEDER: Just one moment.
The Tribunal has no questions either. Thank you very much for coming to assist the Tribunal.
THE WITNESS: Thank you.
(Witness steps down.)
PRESIDENT VEEDER: Claimants will resume.
Do you need a five-minute break to get organized?
MR. LEGUM: Well, I guess the question is whether the Respondent wishes to hear from Mr. Johnson or are we done?
PRESIDENT VEEDER: Forgive me. I forgot. Of course, Mr. Johnson.
Do you want five minutes?
MR. BIGGE: Yes. Give us five minutes.
PRESIDENT VEEDER: We'll take five minutes.
MR. BIGGE: Thank you.
(Brief recess.)
PRESIDENT VEEDER: Let's resume.

MR. BIGGE: Thank you, Mr. President.
I think we were able to pose all of our questions to Mr. Bradshaw. So we will not have any questions for Mr. Johnson.
PRESIDENT VEEDER: Thank you very much.
So, Mr. Johnson is effectively released, but we now return to the Claimants for the continuation of the presentation of their case.
Do you need a few minutes to get organized or do you want to proceed?
MR. LEGUM: We do, indeed, need a few minutes to get organized. So if we could, perhaps, take a 15-minute coffee break?
PRESIDENT VEEDER: Let's take a 15-minute break, and we'll come back at 25 past 10:00.
Thank you very much.
MR. LEGUM: Thank you very much.
(Brief recess.)

CONTINUED OPENING STATEMENT BY COUNSEL FOR CLAIMANTS

PRESIDENT VEEDER: Let's resume. The Claimants have the floor.
MR. LEGUM: Mr. President, what we thought we

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might do is begin by asking the question put forward by Mr. Crook yesterday concerning where the different names that have been coming up at FDA CDER fit into the structure, and so at the break, we've handed out Exhibit C-489. This is an organization chart for the Division of Manufacturing and Product Quality that dates from April 2009.

This is a document that we found on the FDA Web site which provided, so far as we've seen, the best kind of general overview the organization of the relevant office. So perhaps I'll begin at the top of the chart.

So at this point in time, this was called the Division of Manufacturing and Product Quality. My understanding is that there had been some significant reorganization of that in the meantime, and it's now called the Office of Manufacturing and Product Quality.

At the top where you see "Office Director, Deborah M. Autor," that's referring to the Office of Compliance in CDER. So the Division of Manufacturing and Product Quality is part of or reports to the

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Office of Compliance, and the people that work in it, as I understand it, are in the Office of Compliance.

So in 2009, Deborah Autor was the director of the Office of Compliance and above her was Janet Woodcock, who was the officer of CDER. Joseph Famulare, whose name appears in some of the documents was at that time the deputy office director. And Rick Friedman was the director of the Division of Manufacturing and Product Quality.

If you look down on the right, at the next level in the organization chart, you see a name that's come up several times, which is Edwin Rivera-Martinez, who was the branch chief at this time for Manufacturing Assessment and Preapproval Compliance Branch.

Then if you look below Mr. Rivera-Martinez on the left side, there's a reference to the international compliance team. And below the name that's listed there, which is the acting team leader at the time, you see a number of other names, some of which include people whose names have come up frequently in this arbitration, one being Carmelo

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Rosa, Dr. Rosa, and Hidee Molina, each of whom worked on the Apotex case, as well as Kristy Zielny.

My understanding is that shortly after this, Dr. Rosa became the acting team leader for the international compliance team continuing to work with Mr. Rivera-Martinez. And then at some later point there was a reorganization of the office, as I mentioned, and the organizational structure becomes a little bit more difficult to reconcile with this chart.

But that, for the Tribunal's information, is at least our understanding of it. Obviously, the United States will have a much better understanding of these things.

PRESIDENT VEEDER: Can you tell us what the red ink means? Why some are in black and some in red?

MR. LEGUM: I think it's because this was a presentation. And if you turn to the title page of the presentation, they were focusing on the Case Management and Guidance Branch. And so I suspect that for those purposes, they put that branch in red.

I'd like to turn the floor over to

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Anne-Sophie Dufêtre to address the comparators.

MS. DUFÊTRE: Good morning, Mr. President, Members of the Tribunal.

In this part of our presentation, we will address each of the comparators selected by Apotex starting with Teva, followed by Sandoz, Hospira, Baxter, and Perrigo.

For each of these comparators, we will show that they were in like circumstances with Apotex and that each of the comparators was afforded more favorable treatment than Apotex.

And, finally, for each of these comparators, we will address the U.S. justifications as to why these comparators did not receive any enforcement action on the part of FDA and we will rebut the U.S. justifications.

So the way we have organized the presentation today--and I apologize; we forgot to print out the agenda--but we will be alternating, Mr. Legum and myself. So I will start with Teva and then we'll follow up.

Before I do that, before I turn to Teva,

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10:34:21 there is one quick argument that I need to address. It is the U.S. argument that the Import Alert did not constitute treatment. Here, all the U.S. is saying is that the Import Alert did not constitute treatment because it did not relate to Apotex-U.S. or Apotex's Marketing Authorizations. Clearly, this argument is just a repetition of the U.S. "relating to" argument made in the jurisdictional section, and as we've explained yesterday during our presentation on jurisdiction, the record does not support the U.S. argument. The same showing that we made to demonstrate that the Import Alert did, in fact, relate to Apotex-U.S. and to Apotex Marketing Authorizations, this showing also establishes that the Import Alert accorded treatment to Apotex-U.S. and to the Marketing Authorizations.

So I will now begin with the comparators, and I will start with Teva.

Teva Pharmaceutical Industries Limited is an Israeli company, and it is the world's leading generic pharmaceutical company. It is also a leading provider of generic drug to the U.S. market. Teva has 56

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10:35:51 manufacturing facilities across the globe, including one in Jerusalem and one in Irvine, California. Teva sells its product in the United States through various distribution companies that are supplied by Teva's manufacturing facilities. Teva also owns over 600 Marketing Authorizations in the United States.

As noted in Mr. Bradshaw's and Mr. Johnson's Expert Reports, during the relevant time period, FDA issued two Warning Letters to Teva. The first Warning Letter was issued in December 2009 to Teva Parenteral for its facility in Irvine, California, and the second Warning Letter was issued to Teva Pharmaceuticals, the Israeli company, in January 2011 for the site in Jerusalem. That second Warning Letter was closed out only seven months after it was issued following a re-inspection by FDA of the Teva Jerusalem facility.

So I will now start with like circumstances and demonstrate why Teva is in like circumstances with Apotex.

With respect to Teva Parenteral, the U.S.-based facility, the U.S. has not disputed that this facility is in like circumstances with Apotex

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10:37:28 other than the fact that the facility is located in the U.S. and, therefore, cannot be placed on Import Alert. We have shown that this is a purely legal defense and it should be rejected.

With respect to Teva Pharmaceuticals, the Israeli company, the U.S. accepts that it was in like circumstances with Apotex because the Jerusalem facility was eligible for Import Alert 66-40. And here I refer to the U.S. Counter-Memorial at Paragraph 334.

Let me now go over the facts that demonstrate the like circumstances between Teva and Apotex. First, like Apotex, Teva is an investor in the pharmaceutical industry. Second, like Apotex, Teva has investments in the United States in the forms of scores of Marketing Authorizations and enterprises which distribute in the United States products manufactured by subsidiaries of Teva.

Three, that Teva is the number-one seller of generic drugs in the United States.

Four, Teva competes on the U.S. generic drug market with Apotex.

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10:38:52 Five, in July 2009, FDA found serious cGMP deviations at Teva Parenteral's Irvine site.

Six, FDA issued a Warning Letter for the Irvine site. That Warning Letter, as I said, was issued in December 2009. Then, in September 2010, FDA found other cGMP deviations at Teva's facilities in Jerusalem, and this inspection was also followed by a Warning Letter issued in January of 2011. Therefore, Teva received two Warning Letters for two separate facilities within a year or so--13 months, to be accurate.

And, finally, the U.S. has not--does not dispute that Teva had repeat violations, notably for the endotoxin contamination.

Now, there are other circumstances that should also be taken into account with Teva. And I need to make it very clear that these circumstances are not like Apotex's circumstances. However, these circumstances go to the treatment that was received by Teva and, therefore, they should be taken into consideration.

I have tried to organize this set of

circumstances in three separate topics. And the first one goes to the nature of the cGMP violations and the fact that they were more serious than the ones observed at Etobicoke and Signet and that they, in fact, resulted in a public health risk to U.S. consumers.

The first indication of that is the fact that Teva had to do several recalls. For instance, it did a recall due to endotoxin contamination, and that's the problem that contaminated a number of patients in the United States.

Teva also had to do recalls because of overthick tablets. It had to do a recall for noncompliance with cGMPs. It had to do yet another recall for low tablet weights or discoloration.

I also note that the major recall, the one that was due to cGMP noncompliance, that recall was FDA-initiated, which means that it was officially requested by the FDA as opposed to voluntarily proposed by the firm.

As we also explained, Teva's products contaminated at least 41 patients in the United States

because of the presence of endotoxin. Endotoxins are part of bacteria cells that can--it is my understanding that it can cause like a severe fever and even death, and actually this fact was noted in a letter from FDA to Congress. So, the seriousness of the endotoxin contamination problem at Teva is not disputed by FDA.

Also, shortly before FDA issued a closeout letter for Teva Jerusalem--so that closeout letter again came in September 2011--shortly before that, glass was found in an active pharmaceutical ingredient produced at the Teva Jerusalem site. FDA also inspected other facilities--in particular, in Virginia and Canada--and FDA found serious problems there as well.

I'm moving, now, to the second set of circumstances that are specific to Teva, and it is the fact that Teva had ample opportunities to propose Corrective Actions before FDA decided whether or not to take enforcement action against Teva.

So, we know that Teva Parenteral submitted at least six responses to the FDA's Form 483 issued for

the Irvine inspection in July 2009. Teva also had the opportunity to respond to the Form 483 concerning the Jerusalem inspection. That response was submitted in October of 2010. And FDA took the firm's response into account before it issued the Warning Letter.

And also, as noted in the Teva Warning Letter--as noted in the Teva Warning Letter, Teva had three weeks to schedule a regulatory meeting and prepare its response.

And concerning the last set of circumstances which are specific to Teva, they go to the swiftness of FDA's re-inspection and the closing out of the Teva case.

So, again, the Teva Warning Letter for Jerusalem was issued in January 2011. In June of 2011, FDA re-inspected Teva Jerusalem. And what is interesting here is that FDA acknowledged that it was "inspecting Teva into compliance." And I am quoting here an internal e-mail, FDA internal e-mail, where Mr. Rosa made that statement, and you now have that on the screen. It is Exhibit C-574.

In that same e-mail chain, it is also clear

that Dr. Rosa communicated exactly what was needed for a closeout. And can see that in the e-mail where it says that "Carmelo"--this is Dr. Rosa--"also communicated with Fran"--this is Fran Seskers of Teva--"last week what was needed for closeout."

And again, as a result of that, FDA issued a closeout letter for Teva in September of 2011.

The U.S. does not dispute any of these circumstances. In particular, the U.S. does not dispute the fact that FDA found cGMP problems at two Teva sites. The U.S. does not dispute that FDA issued two Warning Letters to Teva in less than 13 months. The U.S. does not dispute that Teva's cGMP violations were serious and led to the contamination of patients. And the U.S. also does not dispute that Teva had repeat violations, in particular for the endotoxin bacteria.

Also, with respect to Teva, FDA made it clear that it expected the firm to propose global corrective action as opposed to site-to-site-specific remediation. And this was made clear by Mr. Friedman in regulatory meeting between FDA and Teva held in

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October of 2010. And that exhibit is now on the screen.

And the last point that the U.S. does not dispute is that Teva Jerusalem was in like circumstances with Apotex because it could be placed on Import Alert.

Now that we have reviewed the circumstances, both like and specific to Teva, I will move on to treatment. The U.S. does not dispute that FDA took no enforcement action against Teva. As we note, Teva Jerusalem was not placed on Import Alert. There was no market ban against any Teva products. FDA refused to take a cooperate action or a cooperate approach towards Teva, one that would have covered the two sites, Irvine and Jerusalem, together. Teva Jerusalem was also quickly re-inspected into compliance. Again, FDA issued the closeout letter only seven months after the Jerusalem Warning Letter was issued.

Teva Jerusalem and Teva Parenteral were given opportunities to address FDA's concerns before FDA took a decision with respect to any enforcement actions or the lack thereof.

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In contrast, Apotex received less favorable treatment. Apotex was placed on Import Alert. The Apotex products were banned from the U.S. market for two years. FDA took a corporate approach against Teva, arguing that Etobicoke and Signet were under the same quality control system. FDA refused to re-inspect Teva into compliance--sorry; Apotex. FDA refused to re-inspect Apotex into compliance. And you can see that on the exhibit which is now on the slide, in this exhibit, which is C-523, where Mr. Rosa also noted that FDA does not intend to serve as Apotex's QA/QC unit, nor re-inspect them--inspect them into compliance.

ARBITRATOR ROWLEY: Can I just ask a question because I've been a little uncertain in the last two days about the difference between a re-inspection when requested by a Party that has been inspected and observations have been made and a re-inspection into compliance.

What is the difference?

MR. LEGUM: So, as I understand the difference--and it is, perhaps, a question for

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Witnesses--but a re-inspection is intended to verify that a firm has taken sufficient corrective actions for an enforcement action to be lifted.

And so re-inspecting into compliance, as I understand the terminology, is when FDA goes to a firm's facility, identifies problems, and tells the firm exactly what to do to address the problems.

That's to be distinguished from the situation that Apotex found itself in, where FDA, rather than doing that and proposing--telling Apotex what it needed to do precisely to meet FDA's concerns, simply carried out the re-inspection as an audit of the facility. So, that's my understanding of it.

ARBITRATOR CROOK: Can I ask a related question?

Other than the one e-mail we were shown with the reference to re-inspection into compliance, is there any evidence in the record that indicates that is what was done here?

MR. LEGUM: For Teva.

ARBITRATOR CROOK: Yes.

MS. DUFÊTRE: No, because there are very few

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exhibits that were produced--very few documents that were produced during document production. We know that the U.S. has said they produced over 10,000 pages of documents, which is correct.

But as we've explained in our last pleadings, out of these 10,000 pages of documents, there were only 62 documents that had the word "Teva" contained in them, and most of the these documents contained the word "Teva" just in passing. For instance, "What's going on with the Teva?" And so, therefore, there was not much content with respect to Teva in these documents. And it is telling that the U.S. has only produced like three exhibits pertaining to Teva, and I'll come to that later in my presentation.

So, in fact, we are left with very little evidence, and most of our case is based on the evidence which is in the public domain, such as Warning Letters and recalls and closeout letters, but this one e-mail about inspecting into compliance is the only one in the record.

PRESIDENT VEEDER: I'm going to refer to Exhibit C-424. I see it later in your slides.

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10:53:29 Do we have the list of the attendees for that exhibit? We have at the moment a redacted form, but there are some attachments which include the attendee list, and also an FDA Teva presentation.

Is that in the full exhibit that was disclosed to you, or is that something that's been not disclosed?

MS. DUFÊTRE: If you can just give me two seconds to look it up.

To our knowledge, we haven't seen the attachments.

PRESIDENT VEEDER: Thank you.

ARBITRATOR ROWLEY: Does that mean that the attachments were not produced?

MR. LEGUM: It does, so far as we're aware.

MS. DUFÊTRE: Thank you.

So, if we go back to the slide which is now on the screen, I was comparing the closeout and the swiftness that--with which FDA closeout the Teva case. Whereas, for the Import Alert with respect to Apotex, it took several months after the inspections and the clearance of the facilities for the Import Alert to be

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10:55:39 lifted. And as the Tribunal may recall, it also took FDA a long time to re-inspect Teva--sorry; Apotex. And the re-inspection was initially scheduled in November of 2010, but it was delayed until January/February 2011.

So here again, our position is that the treatment was not the same in the swiftness or not towards re-inspection and clearance.

And, finally, the last point on differential treatment is that contrary to Teva, Apotex was not given any opportunity to address FDA's concerns before FDA decided to place Apotex on Import Alert.

And I need to pause here for a minute and, perhaps, go through the main events in the chronology again. I mean, Mr. Hay did that yesterday, but I think it's important to recall the major points.

So, on August 13, while the Signet inspection was still underway, FDA's CDER Office of Compliance began to update a draft of the Import Alert recommendation. On Friday, August 14, during the closeout meeting with Apotex, the inspectors required Apotex to consider on the following Monday. Over the

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10:57:15 weekend, Apotex had no time to confer with consultants. Apotex made the decision to hire Jeff Yuen and to recall over 600 batches of products as a precautionary measure and goodwill gesture. But, obviously, in just a weekend, Apotex did not have time to develop a full remediation plan.

On Monday, August 17, even before speaking with Apotex, CDER inspector referred to the Import Alert as a fait accompli, and you will see that in Exhibit C-371.

In the afternoon of the Monday, August 17, Apotex called FDA as planned. During that call, Apotex committed to voluntary recall over 600 batches. FDA then asked Apotex whether it would continue distribution in the United States. Apotex responded that it intended to continue distribution, and at this point FDA did not take matters further. FDA did not request that Apotex stop all distribution in the United States. But Apotex, however, had clearly committed to stop distribution--production and distribution for some of the products with which FDA took issue during the Signet inspection.

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10:58:51 Again, this is at Exhibit R-43, on the last page of the document, where you can see the comment by Mr. Lance Lovelock, who was then Apotex head of quality control.

It is also important to understand that at that time, Apotex had never received a Warning Letter before. I mean, the first Warning Letter was the Etobicoke Warning Letter that was received in June, so it was very, like, shortly before. And, therefore, Apotex, because it had not received Warning Letters before, had no prior experience with FDA's expectations in terms of proposed corrective actions. And this was explained by Mr. Desai in his First Witness Statement.

So, going back to the chronology, we know that this phone call between Apotex and FDA took place in the afternoon of August 17. And then a few days later, on August 25, CDER requested that both Etobicoke and Signet be placed on Import Alert.

So on the slide on the screen you have all of the references to the exhibits of record, just for the Tribunal's convenience.

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11:00:21 So based on this record, it is clear that FDA did not give Apotex sufficient time and opportunity to propose Corrective Actions before it was placed on Import Alert. In fact, FDA had already made up its mind. FDA decided to recommend the Import Alert before it completed its review of Apotex's response to the Etobicoke Warning Letter.

As repeatedly pointed out by FDA, the Import Alert was adopted only 10 business days after the close of the Signet inspection, and FDA decided to take the Import Alert before Apotex even had a chance to submit its response to the Form 483 for the Signet inspection. That response was submitted on September 3 of 2009. It was timely submitted, but by then FDA had already placed the firm on Import Alert.

So contrary to Teva and all of the other selected comparators, Apotex was not given any opportunity to propose Corrective Actions before FDA considered enforcement action against Apotex.

I will now move on to the third part of my presentation on Teva and rebut the U.S. justifications concerning the treatment received by Teva. So, again,

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11:01:57 the U.S. does not challenge the fact that Teva was in like circumstances with Apotex other than the fact that Teva Parenteral could not be placed on Import Alert.

Likewise, the U.S. does not dispute the fact that FDA took no enforcement action against Teva, Jerusalem or Irvine, but the U.S. instead argues that there were justifications for not taking any enforcement action against Teva.

On this record, however, the U.S. case must fail. There was no valid justification for not taking any enforcement action against Teva while placing Apotex on Import Alert.

So, here, I will first go through the U.S. justifications pertaining to Teva Israel, and then I will look at the U.S. justifications concerning Teva Irvine.

So with respect to Teva Jerusalem, the U.S. is relying on FDA's so-called "risk-based approach."

In a nutshell, the U.S. argues that after reviewing Apotex's and Teva's respective cases, FDA came to different conclusions: The Import Alert for

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11:03:14 Apotex and no enforcement action for Teva. But the U.S. argument on the so-called "risk-based approach" must fail both in law and in fact.

First, the law. The risk-based approach is premised on and evaluation of the facts. By definition, the factual context goes to like circumstances, not treatment. In other words, even if FDA evaluated the factual context of both Teva and Apotex, it does not mean that these companies were treated equally. The treatment here consists of the action that was taken or not taken after FDA evaluated the factual context. Clearly, that treatment was different; again, the Import Alert for Apotex and no enforcement action for Teva.

Now, if we turn to the facts, the U.S. defense must also fail on this record. At the outset, I must say that it is quite difficult to engage with the U.S. on the so-called "risk-based approach" because there is very slight evidence in the record.

The discussion on Teva Jerusalem was only one paragraph in the U.S. Counter-Memorial, and that paragraph is now appearing on the screen. As you can

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11:04:45 see, the argument is quite succinct and it is unsupported.

In Paragraph 337 of the U.S. Counter-Memorial, the U.S. only cited to the Teva closeout letter and to one paragraph in Dr. Rosa's Witness Statement. But neither addresses FDA's risk-based approach.

If we look at the closeout letter--which is now on the screen--that letter does not even mention the risk-based approach. The letter simply states that FDA "completed an evaluation of Teva's corrective actions," and the conclusion was that Teva had addressed the violations contained in the Warning Letter. Again, there is nothing in this letter showing how the risk-based approach might have been applied to Teva.

Similarly, if we look at Paragraph 20 of Dr. Rosa's First Witness Statement, again you can see that it is very general. In this paragraph, Dr. Rosa describes the role of CDER Office of Compliance in initiating enforcement action. But it does not say a wore on Teva Jerusalem. And, similarly, Teva

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11:06:13 Jerusalem is not mentioned anywhere else in the remainder of Dr. Rosa's Statement.

Now, in its Rejoinder, the U.S. invoked for the first time a defense of medical necessity with respect to Teva Jerusalem. But here again, this defense fails to close the gap in the evidentiary record.

During the disclosure phase, the U.S. refused to produce documents pertaining to FDA's risk-based approach concerning Teva, and I've addressed this point briefly in answering one of the earlier questions by the Tribunal, but I think it is worth making the point again.

In the 10-plus document productions by the U.S., the U.S. only produced 62 documents containing the word "Teva." Many of these documents are duplicates or the same e-mail chain is repeated several times--the same e-mail is repeated several times in this chain. And many of these documents that contain the word "Teva" are simply not responsive. And we've addressed that in detail in our Rejoinder on Jurisdiction at Paragraph 68.

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11:07:39 Now, all of the documents pertaining to Teva Jerusalem and Teva Irvine are in the record except for the Form 483 and the EIR, but these documents are very few, and they do not shed light on how FDA applied the risk-based approach to Teva.

It is interesting to note that the U.S. has submitted only three documents pertaining to Teva Jerusalem, and these documents were submitted with the U.S. Rejoinder, not the Counter-Memorial.

Just for the record, these documents are Exhibit R-134--sorry, R-131, which is an FDA e-mail chain dated February 25, 2011; Exhibit R-192, an FDA e-mail chain dated March 21, 2011; and Exhibit R-215, which is Teva Annual Report for the year 2012.

There is no satisfactory record evidence supporting the late argument made by the U.S. on medical necessity. The U.S. has not produced, let alone submitted in the record, the drug shortage analysis that supposedly supports its assertion on medical necessity. Instead, the U.S. relies on a single e-mail chain which is now on the screen and is Exhibit R-131.

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11:09:22 But if we take a closer look at this exhibit, it does not contain the actual drug shortage analysis. And what is more, this e-mail chain only talks about 20 products or so that Teva decided to recall in February 2011. 20 products is really not much for Teva because, as we know, Teva Jerusalem is a huge producing facility, and so it is unclear how this e-mail here could pertain to the drug shortage analysis for all of the products that are manufactured at this site.

The U.S. also fails to explain why the alleged medical necessity could have justified permitting every one of the drugs produced at Teva Jerusalem to remain on the U.S. market while all of the drugs made to made at Etobicoke and Signet were banned.

If this drug shortage analysis pertaining to Teva had been produced, it would have shown which Teva Jerusalem products were medically necessary and which ones were not. But, again, the U.S. failed to produce this drug shortage analysis.

The Tribunal should also keep in mind that it

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11:10:53 is possible to place a firm or facility on Import Alert while making exceptions to that Import Alert for drugs that are medically necessary.

In fact, in the case of Apotex, FDA made one exception to the Import Alert, and that was for a drug called deferiprone, which is a drug used for compassionate use in cancer treatment. And that drug was only provided to 47 patients in the United States by Apotex.

Just to give another example on this point, for Ranbaxy, when Ranbaxy was placed on Import Alert, the FDA made an exception for a product that is called Ganciclovir, and which is manufactured at the Dewas facility.

Under Article 25 of the Draft Articles on State Responsibility, a State can invoke necessity to avoid responsibility for its acts only if the act in question was the only way for the State to safeguard an essential interest against a grave and imminent peril.

On this record, allowing every one of the products made at Teva Jerusalem to remain on the

market was not the only way for the State to safeguard an essential interest against a grave and imminent peril. FDA could have allowed Teva's products that were medically necessary and in shortage, while banning the other Teva products that were not medically necessary or in shortage.

Nothing justifies banning every single product made at Etobicoke and Signet from the U.S. market while allowing Teva to keep all its products made at Jerusalem on the market despite the very serious cGMP violations found at the Teva site.

Furthermore, under Article 25 of the Draft Articles, a State cannot invoke necessity if the State has contributed to the situation of necessity. On this record, the U.S. has contributed to the state of necessity that it now seeks to invoke to avoid its responsibility--international responsibility.

As shown by the U.S.'s own evidence, the Import Alert imposed on Apotex led, in part, to the drug shortage situation in early 2011.

Now we see on the screen the same Exhibit R-131, which pertains to the drug shortage

analysis--the so-called "drug shortage analysis" for Teva in February 2011. And what is interesting here is that it shows that Teva had very large market share that, in part, it had acquired from Apotex after Apotex was placed on Import Alert.

Back in 2009, FDA anticipated that Teva and other companies would be "able to ramp up" and take over Apotex's market share if Apotex was placed on Import Alert.

And, again, if we go back to another exhibit produced by the U.S.--

MR. SHARPE: I'm very sorry so interrupt, but I think these are some of the documents that the United States produced that were designated confidential--

(Conferring.)

MR. SHARPE: Could we just have one moment, please.

PRESIDENT VEEDER: Certainly.

(Pause.)

MR. SHARPE: My apologies for the interruption and the objection. We do not have an

objection to this continuing on the live feed. Thank you.

PRESIDENT VEEDER: Thank you. Please continue.

MS. DUFÊTRE: So we were looking at Exhibit R-192, which an e-mail on March 2011 from Valerie Jensen who deals with drug shortage analysis. And, again, this e-mail makes clear that Teva, in 2011, had the majority of the market because Teva picked up market share when Apotex and others were placed on Import Alert.

So, because of the Import Alert imposed on Apotex, all drugs made at Etobicoke and Signet were banned from the U.S. market and, as a consequence, Teva was able to take over Apotex's market shares for these products.

In fact, if we look, now, at Exhibit C-574, in 2011--in August of 2011, Teva was described by FDA as the biggest manufacturer of most chronic medications needed by U.S. patients. And here, again, there is a reference to the fact that Teva was able to become a dominant player when it took market shares

from Apotex and others.

PRESIDENT VEEDER: C-574 is a confidential document, isn't it?

MR. LEGUM: Mr. President, as has been alluded to before, the Parties have, in producing documents, taken a precautionary approach and marked many documents as confidential. Our understanding is that the United States--this is a document produced by the United States and that it has no objection to this information being displayed.

However, we're happy to cut feed for this part of the presentation.

MR. SHARPE: Thank you.

Mr. President, we agree that this does not need to be cut for the live feed, but I would note that we concur that we did produce documents with a precautionary notion that we would have an opportunity to subsequently to designate those--that information within those documents that might need to be redacted.

But what we would encourage the Tribunal to be mindful of is if Claimants are seeking to exclude information from the public record simply because it

reflects negatively on Claimants, whereas they are using United States documents that are discussing third-party--that have been designated that were discussing third-party information, even if the specific information is not itself confidential, but shouldn't be using it as a sword and shield in this manner.

PRESIDENT VEEDER: Well, I apologize. That was my intervention, not the Claimants'. I don't think it's a question of the latter situation. It is very difficult for us to police, so we'll just have to leave it to you, but I thought we were getting into a potentially awkward situation.

But if we're not, please continue.

MS. DUFÊTRE: So what the U.S. evidence shows is that the Import Alert imposed on Apotex, in part, was responsible for the drug shortage situation in early 2011. Because of the Import Alert imposed on Apotex and others, Teva became the dominant player in 2011 because it was able to take over shares, market shares, from Apotex.

Now, on the slide which is now on the screen,

we see that Apotex is mentioned along with other companies which were--which also had cGMP problems and which apparently also contributed to Teva becoming the leader on the market in 2011.

However, I want to point out that in 2009, two of the companies mentioned there, Caraco and KV, were not even on the top 25 list of generic drug manufacturers on the U.S. market.

If we look at the market rankings in 2009, Teva was Number 1, Apotex was Number 8, Actavis was Number 13, and Ranbaxy was Number 21. Now, if we compare that with the market rankings in 2011, Teva remained Number 1, Actavis had risen to Number 10, Ranbaxy had risen to Number 17, but Apotex had dropped to Number 24.

So the FDA mentioned five companies which had contributed to Teva's very large market share by 2011. But out of these five companies, Apotex was the only one that dropped position during the Import Alert. The other companies, which had also cGMP problems, all improved their market ranking--or two were outside the top 25 generic list, as I said.

The record shows that the Import Alert against Apotex largely contributed to the situation of necessity that the U.S. now seeks to invoke. Based on the Draft Articles on State Responsibility, the U.S. necessity defense must be rejected.

The U.S. has also raised a new argument in its Rejoinder; namely, that FDA feared that Teva would voluntary shut down its Jerusalem facility. And this argument is made at the U.S. Rejoinder at Paragraph--in the U.S. Rejoinder at Paragraph 279.

Again, the only document that the U.S. relies on for this proposition is the same FDA e-mail chain that we have already looked at, this Exhibit R-131. But this evidence contradicts the U.S. allegation that FDA feared that Teva Jerusalem would shut down.

If we take a closer look at this e-mail chain, Dr. Rosa clearly wrote on February 25, 2011 that Teva Jerusalem "is not shutting down...we have no information that the firm intends to shut down the site."

And there is one last argument that the U.S. raised for the first time in its Rejoinder with

respect to Teva, and it is the fact that FDA detained shipments from Teva Jerusalem even though that facility was not placed on Import Alert. This argument is made at Paragraph 280 of the U.S. Rejoinder.

But the detention was Teva products was only temporary. And more importantly, the Teva products in question, the products that were initially detained, were finally eventually allowed to be imported although they were deemed to violate the Food, Drug, and Cosmetic Act.

In contrast, none of Apotex's products from Etobicoke and Signet were allowed to--none of the product was allowed to reach the U.S. and the distribution facility there, Apotex-U.S., during the two years that the firm was placed on Import Alert.

So to sum up, the evidence of supposed medical necessity is unsatisfactory. There is no evidence establishing such a thing. There are only e-mails making summary reference to some degree of medical necessity for approximately 20 products that Teva had decided to recall. Nothing in the record

suggests that there existed a medical necessity for all products that were produced at Teva Jerusalem site.

What the record clearly shows, however, is that the U.S. contributed to the situation of medical necessity by placing Apotex on Import Alert. As a result, the U.S. cannot invoke necessity to justify the more favorable treatment that was accorded to Teva.

I will now move on to the--

ARBITRATOR CROOK: I'm just having a little difficulty getting my mind around the movement of the ILC definition of "necessity" into necessity for purposes of their internal regulatory judgments.

Do I understand correctly that you're saying as a matter of international law, they cannot claim medical necessity because they do not fulfill the ILC's requirements? Is that the position?

MR. LEGUM: I think the way that I would frame it is that one can view the ILC Draft Articles as applying either directly, as addressing the issue of medical necessity that is invoked here--so applying

to a defense of necessity on medical grounds as well on any other grounds--or one can see it as applying by way of analogy. And in looking at a situation where the only justification that is being asserted for granting treatment that would otherwise violate a treaty is necessity. And under those circumstances, it is our submission that the ILC's Draft Articles approach provides a useful way of addressing that question.

PRESIDENT VEEDER: I was going to reserve my question until later, but now that it's being raised, I'll pursue it.

I don't see necessity under international being pleaded as a defense by the Respondent. What I see in Paragraph 337 of the Counter-Memorial is a plea that there is a discretion applying a risk-based approach, and then we list the factors--or the Respondent lists the factors assessing the seriousness of the violations, the risk of those violations to consumers, the company's responses to the violations, and whether the products may be medically necessary and in short supply. But that's not a defense of

necessity.

And when we look later in that paragraph, it's the assertion that this assessment is fact specific, and one of the facts, they say, is if people need the drugs, there may be more benefit in allowing the drugs to go through with a risk than in withholding them.

But I don't see that--even by analogy at the moment--as invoking a sense of necessity under international law. If you'd like to go back on that, it would be very helpful or can you come back to it later.

MR. LEGUM: I guess what I'll do is I'll give a short answer now and then we'll come back to it later on.

Again, if one is looking at this from the perspective of a like circumstance analysis, our submission is that regardless of whether you view this as a necessity defense--and it is analogous to a necessity defense--but even if you don't view it as a necessity offense, the approach of the Draft Articles of State Responsibility is informative in analyzing

the reliance of the United States on this type of necessity as the only circumstance that justifies the less favorable treatment that it accorded to Apotex.

And in our submission, it does make sense. If you're invoking necessity and yet only 5 percent of the products produced at a facility are, indeed, medically necessary, it's not a complete explanation to the less favorable treatment that is accorded. If you are invoking necessity and you yourself have contributed to that state of necessity, then that, again, is not a satisfactory explanation from our point of view.

But as I said, I'll take that on board and come back to it.

PRESIDENT VEEDER: Okay. Thank you.

MS. DUFÊTRE: Okay. So I will now move on to Teva Irvine.

So, with respect to Teva Parenteral, in the Counter-Memorial, the U.S. did not dispute that this facility was in like circumstances other than its location. The U.S. argued as part of its argument on treatment that there was no need for enforcement

action against Teva Parenteral Irvine facility since the firm voluntarily committed to shut down production at Irvine. And this is at Paragraph 336 of the U.S. Counter-Memorial.

Then in its Rejoinder, the U.S. argued that FDA "evaluated the circumstances with respect to Teva Irvine and decided that there was no need for enforcement action." So, here I refer to the Tribunal to Page 135 of the U.S. Rejoinder at Paragraph 265.

So, it seems to be--it seems that the basis for the U.S. argument seems to be a moving target, but whether the argument is framed under "treatment" or under "circumstances," the argument fails.

As already demonstrated by Mr. Legum, voluntary actions cannot be equated with State action. Teva Parenteral's voluntary acts do not qualify as "treatment." And even if the U.S. assertions were going to circumstances, these circumstances on this record did not justify granting Teva Parenteral more favorable treatment than Apotex.

The shutdown theory is also a surprising one. It does not offer a justification for the difference

in treatment under FDA practice. And here I would like to refer the Tribunal to the Expert Opinion of Mr. Bradshaw and Mr. Johnson. They explain that FDA's historic practice has been that a firm cannot avoid being placed on Import Alert by voluntarily ceasing all operations.

Now, I will briefly recap the key points about Irvine just for the sake of clarity. So, as I've mentioned before, Irvine was inspected by FDA in 2009. Teva Parenteral had several opportunities to respond to the FDA's Form 483. FDA later issued a Warning Letter to Teva Parenteral in December of 2009. And this Warning Letter cited very serious cGMP violations, again with respect to the endotoxin contamination.

So, you can see a few of the problems now on the screen. And it is also interesting to note that Teva Parenteral had already received multiple prior Warnings, and that the violations that were observed were all repeat violations.

As I have also mentioned, Teva's contaminated products injured a number of patients in the United

States, and Teva had to recall numerous products, including the drug that it makes which is called propofol--and that's the drug that killed Michael Jackson, not that it has anything to do with Teva, but I think it's...

(Comments off microphone.)

MS. DUFÊTRE: Going back to my presentation, FDA took no enforcement action against Teva Irvine or Jerusalem. FDA did not even know that Teva Parenteral was shutting down. And you can see that in Exhibit C-572, which is an FDA briefing on Teva where FDA said that the last time Teva decided to shut down, it did so without notifying the Agency. It is, therefore, hard to see how the so-called voluntary proposed shutdown could have been a determinative factor in FDA's decision-making process with respect to Teva.

The shutdown started in the sector quarter of 2010, while the Warning Letter was issued in December 2009.

So, again, Teva had several months to propose Corrective Actions, including that shutdown. The

shutdown was also temporary. It started in the second quarter of 2010. And in April 2011, Teva Parenteral resumed its manufacturing activity.

Our position is that the shutdown theory has no support in fact. FDA did not force Teva Parenteral to stop production at Irvine. The Import Alert, in contrast, was imposed on Apotex and it forced Apotex to shut down its production entirely for the U.S. market for the Signet and Etobicoke sites.

FDA was not notified when Teva Parenteral decided to temporarily shut down its Irvine facility and, therefore, it could not have been a decisive factor when FDA decided to take or not enforcement action against the firm in December of 2009.

TEVA received a Warning Letter in December 2009, but it was not until much later, in April 2010, that it decided to shut down. So, again, like the firm had four months to propose Corrective Actions here, in particular, in the form of the voluntary shutdown, when Apotex, in contrast, was placed on Import Alert only 10 business days after the close of the Signet inspection.

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11:37:24 ARBITRATOR CROOK: Can I ask a question here? We've got these two SEC filings. One refers to execution of a remediation plan required by the FDA. The second refers to working with the FDA.

Do we have--is there anything else in the record besides these that addresses the interaction between FDA and Teva during this period?

Do we know whether this filing addresses the Irvine plant, or is this Teva globally?

MS. DUFÊTRE: There is one evidence in the record--

ARBITRATOR CROOK: First of all, question: Do we know--I'm too blind to read this, so maybe you can tell me. Do we know whether these two relate to the Irvine plant, or do they relate to Teva globally?

I can't read that either, I'm sorry. Curse of old age.

I don't want to hold up proceedings, we can inspect the document. I don't want to use up all your time, but, perhaps, we could get--at this point, I don't have a readable copy of the document that would be usable.

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11:39:22 MS. DUFÊTRE: We'll check that information, but to the best of our knowledge, the only shutdown for Teva was the shutdown at Irvine.

ARBITRATOR CROOK: Okay. Well, and then the next question is--and you can advise us in due course--is there anything else in the record relating to the alleged cooperation between Teva and FDA that is discussed at two points in this Securities Exchange Commission filing?

MS. DUFÊTRE: Well, again, because the U.S. has not submitted any responsive documents on Teva except the three--

ARBITRATOR CROOK: So the answer is, "No, this is what we've got"?

MR. LEGUM: Well, there is also the minutes of the meeting between FDA and Teva that the President referred to in his earlier question.

ARBITRATOR CROOK: Okay. All right. Thank you very much.

MS. DUFÊTRE: There is one last point that I wanted to make on this shutdown theory. Even if Teva voluntarily shut down production at Irvine facility,

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11:40:33 Teva was free to resume production and distribution of Irvine products whenever it wanted, without any involvement from FDA. Apotex, on the other hand, had to go through FDA's re-inspection and clearance, and as the Tribunal is aware, this took quite some time.

And one final observation on the Teva shutdown. The shutdown at Irvine lasted for about a year, while the Import Alert on Apotex lasted for two years, so double the amount of time.

So in conclusion, a voluntary shutdown by Teva Parenteral does not constitute treatment by the U.S. under the terms of Articles 1102 and 1103. There is no dispute as to the treatment given to Teva. The U.S. did not take enforcement action against that firm. In contrast, Apotex was placed on Import Alert. Teva was both in like circumstances with Apotex and it received more favorable treatment than Apotex. It follows that the U.S. breached Article 1102 and Article 1103 of the NAFTA.

This concludes my presentation on Teva.

MR. LEGUM: Very good. Mr. President, just before taking up the next comparator in our list,

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11:42:11 which is Sandoz, I've now found the reference in that exhibit that we were looking at before, the Annual Report for Teva, and it is clear that that does relate to the Irvine facility.

So the precise reference is R-215. It's at Page 61.

ARBITRATOR CROOK: Thank you very much.

MR. LEGUM: You're welcome.

I begin now to address Sandoz and Novartis. So Novartis AG is the holding company of the Novartis Group. That holding company is incorporated in Switzerland. Sandoz is the generic business of Novartis. Sandoz International GmbH is a Novartis subsidiary incorporated in Germany. Sandoz Inc. is a Novartis subsidiary incorporated in the United States. Sandoz Canada Inc. is a Novartis subsidiary incorporated under the laws of Canada.

Novartis, or I guess the combination of Sandoz and Novartis, which I'll refer to as Sandoz/Novartis, has over 600 Marketing Authorizations in the United States. Sandoz products are manufactured by Sandoz/Novartis manufacturing

companies and distributed in the United States by Sandoz/Novartis subsidiaries.

In 2011, FDA took a coordinated approach and inspected three different facilities of the Sandoz group. One was in Broomfield, Colorado, operated by Sandoz Inc. One was in Wilson, North Carolina, also operated by Sandoz Inc. And one was in Boucherville, Quebec, Canada, operated by Sandoz Canada Inc.

Novartis/Sandoz responded to inspectional observations for each inspection in May, July, and August, 2011. After reviewing Sandoz's responses, FDA issued a corporate Warning Letter for Novartis in November of 2011, and that is now on the screen.

This Warning Letter covered cGMP violations at all three facilities.

Now, as Mr. Bradshaw and Mr. Johnson have explained, FDA takes such a corporate view when it suspects that the corporate entity or group is not providing sufficient oversight and control of the state of compliance at its facilities.

The Warning Letter noted that the cGMP violations at the Canadian facility, Boucherville,

were all repeat violations from prior inspections. Similarly, the cGMP violations at the Wilson facility were repeat violations cited in a prior Warning Letter issued to Sandoz Inc. in August 2008. To date, FDA has taken no enforcement action against Novartis, Sandoz, or any of the three inspected facilities.

So with this brief introduction, I'd like to turn, now, to "like circumstances."

Now, the U.S. accepts that Sandoz Canada is in like circumstances with Apotex. More generally, the record shows that Novartis/Sandoz was in like circumstances. Like Apotex, Novartis/Sandoz is an investor in the pharmaceutical industry. Like Apotex, Novartis/Sandoz has investments in the U.S. in the form of over 600 Marketing Authorizations and enterprises distribute in the United States products manufactured by subsidiaries of Sandoz.

Sandoz is the second largest generic manufacturer in the world and the leader on the U.S. generic drug market. It competes with Apotex on the U.S. generic drug market. FDA inspected Sandoz's North Carolina facility in March 2008, as I've

mentioned, and found serious cGMP deviations. FDA issued a Warning Letter to the North Carolina--concerning the North Carolina facility in August 2008. In the spring and summer of 2008--2011, sorry about that--FDA found serious cGMP violations at three Sandoz sites, as I've mentioned.

In November 2011, FDA issued a corporate Warning Letter to Novartis covering all three sites. All cGMP violations at Boucherville were repeat violations from prior inspections, and some violations at Wilson were already cited in a prior Warning Letter.

So beside these like circumstances, there were already like circumstances which are specific to Sandoz and relevant to the treatment it received.

First, Sandoz Canada's products created a health hazard. FDA observed crystals in injectable solutions manufactured at Boucherville. Crystallization can lead to patient injury or affect the concentration of the drug and make it less effective. This is what the Warning Letter observed.

FDA also observed inadequate procedures to

prevent contamination of drugs made at Boucherville. If contaminated, a drug is no longer sterile, which will severely injure patients if the drug is administered.

Second, Sandoz had an opportunity to propose corrective actions before FDA decided whether or not to take enforcement action against it. Indeed, the U.S. position is that because Sandoz announced a production shutdown at Boucherville, this action obviated any need to place it on Import Alert 66-40. And I'm referring here to the Counter-Memorial at Paragraph 335.

Third, Sandoz was given ample time to correct problems and, in some cases, was quickly re-inspected.

FDA re-inspected Broomfield in August 2012 and issued a Form 483. This was about nine months after the Warning Letter. The Broomfield site was deemed cGMP compliant about one year after the Warning Letter. FDA has taken no enforcement action against the Broomfield--the Wilson facility.

FDA has taken no enforcement action against Boucherville either.

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11:50:13 The U.S. does not dispute any of these circumstances. So the U.S. does not dispute that FDA found cGMP problems at three Sandoz sites. It does not dispute that Sandoz's cGMP violations were similar to those of Apotex, albeit more serious. The U.S. does not dispute that Sandoz had repeat violations. It does not dispute the corporate nature of the Novartis Warning Letter. And, as already noted, the U.S. does accept that Sandoz Canada was in like circumstances with Apotex because Boucherville was eligible for Import Alert.

Turning to treatment, the U.S. does not dispute that FDA took no enforcement action against Sandoz/Novartis. Sandoz Canada--in other words, the Boucherville site--was not placed on Import Alert. There was no injunction or seizure against Sandoz Canada or Sandoz Inc. banning their products from the U.S. market. FDA took no enforcement against Sandoz/Novartis despite the corporate approach taken in the Warning Letter. Now, FDA re-inspected Broomfield in 2012 and upgraded the firm's compliance status.

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11:51:39 Sandoz was given opportunities to address FDA's concerns before FDA took a decision with respect to any enforcement action or lack thereof.

So in contrast, Apotex was given less favorable treatment. Apotex was placed on Import Alert. The products from Etobicoke and Signet were banned for two years. Both Etobicoke and Signet were placed on Import Alert because FDA took a corporate approach. FDA delayed the re-inspection of Etobicoke. The Import Alert was not lifted until June 2011 for one facility and July 2011 for the other, and Apotex was given no opportunity to address FDA's concerns before it was placed on Import Alert. In these circumstances, Apotex submits, Sandoz received better treatment than Apotex did.

I come now to the U.S. justifications for its treatment of Sandoz/Novartis. The U.S., again, does not dispute that Sandoz was in like circumstances with Apotex with the exception of the location of Sandoz Inc.'s facilities in the United States, which we have already addressed. Nor does the U.S. dispute that FDA took no enforcement action. Instead, the U.S.

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11:53:07 attempts to justify the FDA's failure to act, but the justifications lack support.

I will first look at the justifications with respect to Sandoz Canada and then at the U.S.-based facilities.

With respect to Sandoz Canada, the U.S. argues, in essence, that there was no need for an Import Alert against Boucherville because the firm said it would voluntarily shut down production at this facility. As was already shown for Teva Irvine, the U.S. shutdown theory fails in law and fact.

Now, in law, as we've already recalled, a voluntary action by a private person does not qualify as treatment accorded by a Party under NAFTA Articles 1102 or 1103. Therefore, the shutdown, if it existed--and I'll come to that in a moment--at Boucherville would not qualify as treatment eligible for comparison under Articles 1102 or 1103.

It is also interesting to note the shift in the U.S. theory on Sandoz's shutdown. In the Counter-Memorial the U.S. initially argued that the voluntary shutdown justified not placing Sandoz

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11:54:38 Boucherville on Import Alert and demonstrated that Sandoz did not receive more favorable treatment than Apotex. And I'm referring here to Paragraph 335 of Counter-Memorial.

In its Rejoinder, the U.S. requalified the arguments that it had previously made under the heading of "treatment" as going, instead, to like circumstances, in which the treatment was accorded. Whether considered as treatment or as like circumstances, the arguments concerning Sandoz's shutdown is without support in the record.

Now, from the Counter-Memorial to the Rejoinder, the U.S. also shifted its position as to whether there was a shutdown. In the Counter-Memorial, the U.S. argued that "Sandoz Canada essentially shut down production at its Boucherville manufacturing facility." This, again, is Paragraph 335 of the Counter-Memorial.

The U.S. relied principally on two press articles published in generalist newspapers. And the evidence on this point, Apotex submits, is quite unsatisfactory. The U.S. has submitted no documents

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from Sandoz, from FDA, or Health Canada concerning a shutdown at Boucherville. There is in this record no contemporaneous evidence of the supposed shutdown playing a role in FDA's decision making. And even the news articles put forward by the U.S. do not support the shutdown theory.

If we look at Exhibit R-91, which is currently on the screen, it's an article from the Globe & Mail, Sandoz made clear in this article that it had no plans to close the Boucherville plant. In the Reply, Apotex demonstrated that there was no shutdown at Boucherville, but at best, a production slowdown. In a press release, Sandoz Canada announced that it was temporarily slowing down production, not shutting it down, and then only some production.

The slowdown, however, did not affect the extensive oral solid product line produced at that facility. The same press release makes it quite clear that production at the site--that is, Boucherville--continues. When production continues, it is incorrect to discuss it in terms of having shut down.

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In addition, the solid-dose product lines made at Boucherville were not affected by the slowdown either. The only shutdown at Boucherville was caused by a fire, and that lasted only for a few days. Sandoz announced that a fire had broken out at Boucherville on March 4, 2012.

Because of the fire, production had to stop. Production resumed quickly first partially and then normally on March 12, 2012. Now, the fire could explain the slowdown at Boucherville in March 2012, but it was a Force Majeure event. It had nothing to do with the so-called "voluntary shutdown" invoked by the U.S., and it lasted for only a few days, as I've mentioned.

The Novartis Warning Letter was issued on November 18, 2011. By May 16, 2012, two months after the slowdown, Sandoz was already meeting the vast majority of market needs in Canada. I note that this is not just medical necessity; rather, it's the entire injectable portfolio. In these circumstances, it is difficult to conceive that Sandoz shut down production at Boucherville.

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In short, Apotex demonstrated in its Reply that there was no shutdown but only a temporary slowdown.

In its Rejoinder, the U.S. conceded that, in fact, there was no shutdown at Boucherville. The U.S. also conceded that it was clear from the beginning that Sandoz's production slowdown would be only temporary. And I refer to the Tribunal to Paragraph 272 of the Rejoinder for this point. Therefore, on this record and as conceded by U.S., there was, at best, a temporary slowdown but no shutdown at Boucherville.

Now, in contrast, FDA imposed the Import Alert on Apotex for two years. The U.S. response is that an Import Alert does not direct a foreign manufacturing facility to stop production. I'm referring here to Paragraph 269 of the Rejoinder. Yet, in practice, the Import Alert did just that. 40 percent of the Etobicoke and Signet production is for the U.S. market. Because of the Import Alert, there was a severe production slowdown at Etobicoke and Signet when the U.S. market was no longer

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accessible. The slowdown was so severe that over 100 people were laid off from production at Etobicoke.

As a result of the Import Alert, Apotex-U.S.'s business was decimated and Apotex-U.S. dropped out of the top generic sellers in the United States.

So the U.S. is, thus, wrong when it states--as it does at Paragraph 269 of the Rejoinder--that Apotex did not stop production at its Etobicoke and Signet facilities when drugs from those facilities were on Import Alert. Apotex had a forced production slowdown at those facilities when it lost access to the U.S. market, its main market besides Canada. Apotex's slowdown lasted for two years. In contrast, Sandoz Boucherville shutdown was voluntary and it lasted for only a few months.

Now, even if the Tribunal were to accept the U.S. shutdown theory, which is not supported by this record, that theory only reinforces Apotex's point that it was treated less favorably than Sandoz. Let's begin with the timing. The Novartis Warning Letter was issued on November 18, 2011. Sandoz announced the

so-called shutdown on February 29, 2012. For three months, between mid-November 2011 and late February 2012, FDA did not do anything in terms of enforcement. Instead, FDA and Sandoz were collaborating, according to statements made in Sandoz's 2012--or 2011 Annual Report, which was issued in 2012.

You will recall that in the case of Apotex, the Import Alert was adopted only 10 business days after the Signet inspection and that Apotex had only one opportunity to speak with FDA before that Import Alert was imposed. In other words, FDA rushed to take action in the case of Apotex and there was no collaboration. FDA allowed Sandoz to propose corrective actions while it denied this opportunity to Apotex.

Now, in the Rejoinder, the U.S. claimed that Apotex was given several opportunities to address the cGMP findings at Etobicoke and Signet, most notably during the August 17, 2009, telephone conference with FDA. And I'm referring here to Paragraph 271 of the Rejoinder.

As discussed earlier, Apotex had no meaningful opportunity to propose remediation actions. FDA had already decided to put Apotex on Import Alert even before the August 17 call took place. Moreover, Sandoz was free to resume production and distribution in the U.S. at any time. FDA did not have to re-inspect the Boucherville facility first. In contrast, FDA insisted on a re-inspection before lifting the Import Alert.

At all times, by contrast, Sandoz has been free to distribute on the U.S. market products made at Boucherville. In fact, the Boucherville slowdown was so painless for Sandoz that it was not even mentioned in Novartis's reports to its Shareholders. By contrast, the shutdown at another Novartis facility in Nebraska was mentioned. And the relevant slide from the Annual Report is on the screen now. In short, Apotex suffered greatly because of the Import Alert, while the so-called "shutdown" was innocuous for Sandoz.

Now, in the U.S. Rejoinder, the U.S. raises a new defense as to why FDA did not take any enforcement

action against Sandoz Boucherville. The new defense is based on FDA's regulatory discretion and, in particular, the U.S. claims that FDA exercised its discretion to ensure that Sandoz Canada exported--excuse me, continued to export medically necessary drugs to the United States.

However, the U.S. has failed to produce any actual contemporaneous drug shortage analysis for Sandoz. There is no evidence in the record showing that placing Boucherville on Import Alert would have created a shortage of medically necessary drugs in the United States. The news articles that the U.S. relies on address only a shortage situation in Canada, not in the United States.

So what you have on the screen is the first of these two newspaper articles relied on by the U.S., and as you can see, it refers to Canadian pharmacies that could run out of important drugs. It does not refer to U.S. ones.

Here's the second article, which, again, refers to the Canadian market rather than to the U.S. market.

Thus, there is no evidence of record supporting the U.S. argument that enforcement action would have resulted in a shortage of medically necessary drugs in the United States. The U.S. allegation that Sandoz supplied certain medically necessary injectable drugs for the U.S. market is a misleading one. Neither the U.S. nor Dr. Rosa cites to any documentary evidence on this.

The record does refer--in evidence submitted by Apotex, the record does refer to one medically necessary product sold from Boucherville into the U.S. But, in fact, Sandoz did not sell this product in the U.S. at the time of the Warning Letter or before--later in 2012. Sandoz was not authorized to sell this product in the U.S.

Instead, after the cGMP findings were made and FDA took no enforcement action, in 2012, FDA invited Sandoz to sell the product in the U.S. to meet an unrelated shortage. The record does not support the implication that this product played a role in FDA's decision to take no action. And I refer the Tribunal here to Exhibit C-448 and C-463, which

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12:08:37 address the situation of this particular product.
So rather than justifying the decision to take no enforcement action against Boucherville, what the record shows is that while for Apotex the U.S. prevented Apotex from selling any of its products in the United States, for Sandoz Boucherville, the FDA not only took no enforcement action, but actually invited Sandoz to sell a product it was not authorized to sell in the United States in order to meet medical necessity--medically necessary needs despite the cGMP violations observed at that facility.
Finally, even if there had been any medically necessary drugs produced at Boucherville for the U.S. market at time of the Warning Letter or in early 2012, which is something this record does not show, the U.S. still fails to explain why it took no enforcement action with respect to the other drugs produced at that facility for the U.S. market.
By contrast, FDA banished Etobicoke and Signet products from the U.S. market except for one product deemed medically necessary for 47 patients. The record demonstrates no justification for this less

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12:10:08 favorable treatment of Apotex.
Now, if I tried to sum up the key points concerning Sandoz Boucherville, I would say this: First, the U.S. does not dispute that Sandoz Canada was in like circumstances with Apotex. The U.S. does not dispute that FDA took no enforcement action against Sandoz Canada. The U.S. attempts to justify the difference in treatment based on the shutdown theory. This theory is wrong both in the law and in the fact. Sandoz's private acts do not amount as treatment by the State under NAFTA Article 1103. On the facts of this case, there was no shutdown at Boucherville, only a temporary slowdown. Sandoz was provided an opportunity to respond to the Novartis Warning Letter and proposed some Corrective Measures, while Apotex was immediately placed on Import Alert with no comparable opportunity.
And despite the production slowdowns, Sandoz kept selling Boucherville products in the United States. The record does not support the U.S. argument based on a supposed shortage of medically necessary drugs in the United States and does not justify the

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12:11:25 failure of FDA to take any enforcement action at all against Sandoz.
Apotex, in short, was treated less favorably than Sandoz Canada in like circumstances.
Now, turning to Sandoz's U.S.-based facilities in Broomfield, Colorado, and Wilson, North Carolina, the U.S. does not dispute Apotex's factors for like circumstances aside from the location of those facilities in the United States.
Similarly, the U.S., in its Counter-Memorial, did not discuss at all the treatment received by Sandoz Inc. in its U.S.-based facilities. The U.S. does not dispute that FDA took no enforcement action against Sandoz Inc.
In its Rejoinder, the U.S. argued that FDA "monitored and evaluated the circumstances" with respect to Sandoz Inc. This is in Paragraph 265 on Page 135. The U.S.'s new allegations have no support.
First, the U.S. argued in the Rejoinder that Sandoz committed $170 million U.S. to remediation efforts at its three facilities. The only evidence in support of this is the Globe & Mail article that is

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12:12:57 now familiar and which is, again, on the screen. There is no other evidence to corroborate this number.
Now, even assuming that it was in February 2012 that Sandoz committed to spend money on remediation actions, that was still three months after the Warning Letter, which was issued on November 18, 2011. The Tribunal will recall that Apotex had only a weekend to present its proposed remediation actions to FDA. The U.S. argues that Apotex, by contrast, had spent significantly less on cGMP remediation as of March 31, 2012, and that this somehow justifies the different treatment.
Now, if we take a look at the exhibit cited by the U.S., Exhibit 53, it contains the slides prepared by Apotex for a meeting with FDA on March 31, 2010.
Now, under Opening Remarks, the last bullet point addresses only external resources committed to ensure that Apotex responded to prior commitments. External resources are resources like consultants. The U.S. here is comparing what Apotex spent on external consultants to what Sandoz spent on improving

12:14:42 internal processes and personnel. This is comparing apples to oranges. Nobody spends $175 million on consultants, not even Sandoz.

The Tribunal will recall Mr. Bigge's questioning this morning referring to Apotex's having hired a large number of additional quality assurance personnel and taking other measures. That's the kind of act by a pharmaceutical company to improve quality systems that results in numbers that could approximate $175 million. Spending on consultants is obviously going to be a small fraction of this.

The second argument that the U.S. makes is that Sandoz committed to changing its leadership at these facilities. And for this it refers to R-208, which is the Novartis Financial Report for the second quarter of 2012.

Now, like Sandoz, Apotex also changed its leadership. And you have on the screen minutes of the September 11, 2009, meeting where Mr. Kay, who was then the President of Apotex, noted that Apotex had parted company with the previous head of Operations where Quality was reporting to. This is not a ground

12:16:20 for distinguishing the treatment of Sandoz from the treatment of Apotex.

Finally, the U.S. argues that Sandoz Inc. committed to slowing down production at its U.S.-based facilities. This allegation is unsupported. The U.S. cites to no evidence, and there is nothing in the record concerning a slowdown at the Broomfield or the Wilson sites.

Therefore, the U.S. overall conclusion that Apotex's remediation efforts were more modest than Sandoz's is without support on this record.

Now, Mr. President, Members of the Tribunal, that comes to the conclusion of my discussion of Sandoz. Of course, I would be happy to entertain any questions that the Tribunal had.

PRESIDENT VEEDER: Again, thank you, but not at this stage.

MR. LEGUM: Thank you.

Now, I recognize that it is 12:15 and not 12:30, but because of the United States admirable efficiency in completing its cross-examination as early as it did, we still are awaiting the printouts

12:17:33 of the slides and other things that we'll need to continue our presentation. So I would propose, if the Tribunal would accept it, that we break for lunch now and resume in an hour.

PRESIDENT VEEDER: We can resume at 1:30. I would suspect that would do as well.

No objection from the Respondent?

MS. GROSH: No objection, Mr. President.

PRESIDENT VEEDER: Let's resume for 1:30.

We'll ask you now, but you can give us the answer at 1:30, how are we doing timewise generally?

MR. LEGUM: I think we're doing very well. I now anticipate that we will either--I think that we will substantially conclude our presentations today and that, if time is required tomorrow morning for us to conclude our presentation, then we will take up a very small part of the morning.

So I would anticipate the U.S.'s case coming on in the morning, perhaps, even on the very first session.

PRESIDENT VEEDER: Thank you. We'll come back at 1:30.

12:18:44 (Whereupon, at 12:17 p.m., the hearing was adjourned until 1:30 p.m., the same day.)

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AFTERNOON SESSION

PRESIDENT VEEDER: If we're all ready, let's resume. Claimants have the floor.

MS. DUFÊTRE: Thank you. We will just pass out the next slides. So maybe I'll just wait for these to be distributed.

PRESIDENT VEEDER: You were also going to give us the agenda which you forgot to give us before.

MS. DUFÊTRE: Yes, we will.

MR. LEGUM: Just to keep the Tribunal apprised, we're still awaiting the delivery of some of the slides for the presentations we'll be giving this afternoon, but, hopefully, they will arrive in time so it will not be interrupted.

PRESIDENT VEEDER: I sure hope so too.

MS. DUFÊTRE: Mr. President, may I proceed?

PRESIDENT VEEDER: Yes, of course.

MS. DUFÊTRE: Okay. Thank you.

So we will resume with Hospira. Hospira is a pharmaceutical company incorporated in the--

Oh, we seem to be having a problem with the screens.

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13:33:00 So, Hospira is a pharmaceutical company incorporated in Delaware. It develops, manufactures, and sells generic drugs among other things. It also sells innovative drugs. The company holds in excess of 300 Marketing Authorizations.

Hospira has a chronic--history of chronic serious cGMP violations at various of its manufacturing facilities. These violations were confirmed when FDA inspected Hospira's Rocky Mount and Clayton facilities in North Carolina in early 2010.

Following this inspection, FDA issued a Warning Letter covering both the Rocky Mount and the Clayton facilities, and that Warning Letter was issued after FDA reviewed the firm's answer to the Form 483.

The Warning Letter was addressed to the CEO of Hospira indicating the need for corporate action. The Warning Letter also recalled the long violative history of Clayton facility and the numerous recalls of injectable drugs contaminated with metal particles.

As noted by Mr. Bradshaw and Mr. Johnson, Hospira had to make several recalls of contaminated products. And, in fact, Hospira's problems were so

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13:34:39 serious that FDA issued a Public Health Advisory concerning Hospira on May 23, 2012. That Public Health Advisory was issue after it was discovered that Hospira's prefilled syringes were overfilled and could lead to overdose in patients.

And you have the relevant, Exhibit C-449, on the screen.

In February 2012, FDA issued another Warning Letter to the CEO of Hospira, this time covering the facility in Austin, Texas. The Warning Letter also followed several recalls by Hospira. That Warning Letter noted that at least 1,400 complaints with--sorry--1,400 leak-associated complaints were received by the firm in the prior three years.

Hospira's problems have kept accumulating, and yet FDA has taken no enforcement action against the company's U.S.-based facilities.

After this brief introduction, I will turn to like circumstances.

Other than the location of Hospira's facilities in the United States, the U.S. does not dispute that Hospira was in like circumstances with

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13:36:11 Apotex.

So if we go through the criteria once again, like Apotex, Hospira is an investor in the pharmaceutical industry. Like Apotex, Hospira has investments in the U.S. in the form of scores of Marketing Authorizations and enterprises which distribute in the United States products manufactured by subsidiaries of Hospira.

Hospira is a leader on the generic drug market in the United States. Hospira competes with Apotex on the U.S. generic drug market.

In early 2010, FDA found serious cGMP deviations at two Hospira sites: Rocky Mount and Clayton in North Carolina, as I've just mentioned. And in April 2010, FDA issued a Warning Letter to the CEO of Hospira covering both of these sites.

Hospira's violations--cGMP violations were repeat violations, and FDA also found cGMP violations at Hospira's Austin Texas facility, which also led FDA to issue another Warning Letter to the CEO of Hospira for this site in February of 2012.

Now, having reviewed the like circumstances,

13:37:44 I will now say a quick word about other circumstances that are specific to Hospira and which are pertinent to the treatment that that firm received.

First, Hospira products created a health hazard. Overfilled syringes that could lead to overdoses forced FDA to issue a Public Health Advisory. There were numerous other problems with Hospira products, such as visible contamination and leaks.

All of these problems were noted in the document that is now appearing on the screen, which was FDA letter to Congress in July 23, 2012.

Second, Hospira had the opportunity to give several responses to FDA and to propose remediation actions. For instance, the Warning Letter for the Rocky Mount and Clayton facilities in North Carolina notes that FDA reviewed the firm's responses before issuing a Warning Letter, the firm responses to Form 483.

Some press articles also mention that Hospira and FDA were working hand and hand on remediation actions. And, in fact, Hospira CEO thanked the FDA

13:39:26 for collaborating with the firm.

Third, FDA was very prompt to re-inspect the Rocky Mount and Wilson facilities. In fact, Hospira Rocky Mount facility was inspected no less than five times in two years, from August 2009 to August 2011, and for each inspection, FDA issued a Form 483.

And this information comes from Exhibit C-333, which is an FDA list of domestic inspections during the relevant time period.

Similarly, Hospira Clayton facility was inspected five times in a little bit over two years, from April 2009 to July 2012, and for each of these inspection, except one, FDA issued a Form 483.

Now, having reviewed "like circumstances," I will now turn to "treatment."

The U.S. does not dispute that FDA has taken no enforcement action against Hospira for its Rocky Mount or Clayton or even Austin facilities. FDA did not ban any of Hospira's products from the U.S. market. FDA took a corporate view of Hospira's cGMP problems, but this did not translate into enforcement action.

13:41:11 Hospira's facilities were quickly re-inspected, and Hospira was given several opportunities to address FDA's concerns before FDA took a decision with respect to any enforcement action or lack thereof.

Now, if we compare that with Apotex's situation, it is clear that Apotex received less favorable treatment. Apotex was placed on Import Alert. All of Apotex's products from Signet and Etobicoke were banned from the U.S. market for two years. Both Etobicoke and Signet were placed on Import Alert because FDA took a corporate approach to towards Apotex.

FDA also delayed the re-inspection of Etobicoke and Signet; and, as a result, the Import Alert was not lifted until June and July 2011 for Etobicoke and Signet respectively. And, finally Apotex was not given an opportunity to address FDA's concerns before it was placed on Import Alert.

In these circumstances, the record shows that Hospira received better treatment than Apotex.

I will now turn to the U.S. justifications

13:42:35 for Hospira's more favorable treatment.

In the Counter-Memorial, the U.S. did not discuss any of Hospira's like circumstances, except for the locations of the facility, as I mentioned before. In the Counter-Memorial, the U.S. also did not discuss Hospira's treatment.

However, in the Rejoinder, the U.S. raised new arguments about Hospira allegedly showing that FDA was justified not to take any enforcement action against Hospira.

Here the U.S. relies mainly on four newspaper articles, which are at R-206, R-207, R-213, and R-216.

PRESIDENT VEEDER: Can you give us reference in the Rejoinder?

MS. DUFÊTRE: The reference to the Rejoinder is at Para 265 on Page 136.

The justifications put forward by the United States have no merits.

The first justification is that Hospira allegedly committed to spend 375 million in remediation. Again, the only evidence in support is a press article dated November 8, 2012. This is R-213.

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But other than this press article, there is no substantiation, no record evidence supporting this number of 375 million spent on remediation costs.

The article also, interestingly, was published in November 2012. As a reminder, FDA issued the Warning Letter to Hospira in April 2010. So there is a difference of more than two years between the Warning Letter and the article mentioning the costs spent on remediation.

So this article cannot constitute contemporaneous evidence of the remediation efforts that Hospira committed to undertake when it received the Warning Letter in 2010.

As reported in this very same article, Hospira CEO noted that the firm's remediation work was costing more than he had twice projected. And this is now on the screen, and the exhibit is R-213.

So what this shows is that FDA, in 2010, did not know how much exactly it would spend on remediation. I also note that the number, 375 million, if accurate, would cover Hospira's both internal costs and external costs.

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This very same article mentions that Hospira was upgrading its IT systems from computer systems to managed batch documentation release to systems that track the training and qualify of their employees.

So clearly the costs--the money spent on remediation went to upgrading the facilities and processes, and it was not just money spent on external consultants.

Hospira Rocky Mount facility was inspected in February and March 2013, and a Form 483 was issued, and that Form 483 listed 20 observations.

Despite all of the repeat violations found at Hospira, the FDA has not taken any enforcement action, and this is even more shocking when we know that new problems, cGMP problems, have surfaced at Hospira, like hair, glass, steel, and brass found in Hospira's product. This was reported in a press article, which is at C-583.

Because of this problem and the contamination in Hospira's product, Hospira had to recall products in October of this year once again. And yet, FDA has not taken any enforcement action against Hospira.

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The U.S. also claims that FDA did not have to take enforcement action against Hospira because the production slowdown--because the firm committed to slow down and shut down its production at the facilities in question.

But, again, the only evidence that the U.S. has put forward in support of this proposition are press articles. The press articles in question note that the shutdown at Rocky Mount lasted for one month.

If we look at Exhibit R-206, which is now on the screen, the article notes that the Rocky Mount facility was temporary shutdown in December 2011 and at the beginning of January 2012, but that by May 1, 2012, it was operating between 60 and 70 percent.

If we compare that to the treatment received by Apotex, again, all production for the U.S. market had to shut down at Etobicoke and Signet while the firm remained on Import Alert.

The U.S. also alleges that Hospira was producing medically necessary drugs that were in shortage, which would explain why FDA did not take any enforcement action against Hospira.

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However, the U.S. does not specify which drugs were specifically medically necessary and in shortage. So once again, there is no evidence supporting the U.S. allegation that a drug shortage analysis would have supported FDA's not taking any enforcement action against Hospira.

And as we noted this morning, in any event, FDA could have taken enforcement actions against Hospira and make exception for these drugs that are medically necessary, if any. But instead of doing that, FDA simply gave Hospira a blanc-seing.

There is one less argument that the U.S. raised for the first time in its Rejoinder, and it concerns the facility in Costa Rica of Hospira, which was placed on Import Alert in November of 2012.

But that facility does not market--does not manufacture drugs. In fact, it manufactures medical devices, specifically infusion pumps. Because that facility manufactures medical devices as opposed to finished pharmaceutical, it is not relevant to our comparison.

And the U.S. recognizes that Hospira's Costa

Rica facility was placed on Import Alert Number 89-40, and this type of Import Alert deals with non-cGMP-compliant facilities manufacturing medical devices, again, not finished drug products.

The U.S. produced, with its Rejoinder, a Warning Letter issued to Hospira's Indian facility in May 28 of this year, but I will simply note that this Warning Letter was issued after Mr. Bradshaw and Johnson submitted their Second Expert Report on May 20, 2013.

Therefore, their conclusion stand, the conclusion being that during the relevant time period, between 2008-2011, they did not locate any Warning Letter issued to a U.S.-owned facility outside of the United States.

So on this record, Hospira was treated more favorably than Apotex in like circumstances and despite the fact that Hospira's quality problems were much more serious and endangered the U.S. customers.

I will now turn the floor to Mr. Legum, who will address Baxter.

MR. LEGUM: Before I do, may I inquire

whether the Tribunal has any questions at this point?

PRESIDENT VEEDER: No.

MR. LEGUM: Baxter International Inc. is a global health care company organized under the laws of the United States. Baxter Health Care Corporation is a wholly owned subsidiary of Baxter International Inc. Baxter Health Care Corporation is also incorporated in the United States.

Baxter manufactures pharmaceuticals, among other things. Baxter products are distributed in the United States and elsewhere through distribution subsidiaries. Baxter holds over 100 Marketing Authorizations in the United States.

Baxter had a chronic corporate-wide history of serious cGMP violations during the period 1997-2011. As noted by Mr. Bradshaw and Mr. Johnson, in their report, Baxter received at least 21 Warning Letters from FDA for multiple business units and facilities during that period; some of which manufactured finished drug products, some of which manufactured other medical products.

FDA inspected Baxter's drug facility in

Jayuya, Puerto Rico, in the summer of 2010.

So for the benefit of Court Reporter, this is J-a-y-u-y-a.

Under the Food, Drug, and Cosmetic Act, as well as the NAFTA, Puerto Rico is part of U.S. territory. FDA found serious cGMP violations at this Baxter facility. Baxter also inspected--FDA also inspected Baxter's Guayama, Puerto Rico, facility in September 2010 and, again, observed violations.

Baxter submitted its response to these observation, and FDA reviewed the firm's answer. And you have on the screen the Baxter Warning Letter, which I'll discuss in a moment, noting that FDA reviewed responses of September 15 and October 20, 2010.

On January 20, FDA issued a Warning Letter to Baxter's CEO covering both Puerto Rican facilities. The Warning Letter emphasized that some of the violations were repeat violations from a prior inspection in 2008. In other words, Baxter had had two years to fix problems before it received a Warning Letter.

Following the January 2011 Warning Letter, FDA re-inspected Baxter's Jayuya facility in April and November of 2011. FDA also re-inspected Baxter's Guayama facility in June 2011.

On July 14, 2011, FDA issued a closeout letter to Baxter. In other words, the Warning Letter was lifted six months after it was issued. FDA took no enforcement action against Baxter. So I turn to like circumstances with this brief chronology behind us. Other than the location of Baxter's facilities in U.S. territory, the U.S. does not dispute that Baxter was in like circumstances with Apotex.

Like Baxter--like Apotex, Baxter is an investor in the pharmaceutical industry. Like Apotex, Baxter has investments in the United States in the form of over 100 Marketing Authorizations and enterprises that distribute, in the United States, products manufactured by subsidiaries of Baxter. Baxter is a leader on the U.S. drug market. It competes with Apotex on that market.

In 2010 FDA found serious cGMP deviations at two Baxter sites. In January 2011 FDA issued its

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13:57:55 Warning Letter to the CEO of Baxter covering both sites. FDA considered Baxter to present repeat violations.

Now, beside these like circumstances, there were other circumstances specific to Baxter and relevant to the treatment it received. These other circumstances are not like those of Apotex. They are specific to Baxter.

First, Baxter's products created a health hazard. The 2011 Baxter Warning Letter noted several product defects that could impact the sterility and stability of Baxter products, including product leaks, bursts, premature activation of the drug, and foreign contamination, including a dead insect found in a Baxter product.

Second, Baxter had the opportunity to give several responses to FDA and to propose remediation actions. For instance, the Warning Letter notes that FDA reviewed the firm's responses to Forms 483 before issuing the Warning Letter. Baxter had at least two years from the preceding 2008 inspection to fix problems, which it failed to do. Baxter, despite

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13:59:31 this, was allowed to keep operating its two Puerto Rican facilities while implementing Corrective Actions.

Third, FDA was very prompt to inspect or re-inspect Baxter's two Puerto Rican facilities after issuance of the Warning Letter in January 2011. It re-inspected Jayuya in April and November 2011. It re-inspected Guayama in June 2011. And FDA was very prompt to issue a closeout letter six months after the Baxter 2011 Warning Letter was issued.

I turn now to treatment. The U.S. does not dispute that FDA has taken no enforcement action against Baxter's facilities in Jayuya and Guayama, Puerto Rico. FDA did not ban from the market any Baxter markets made at these two Puerto Rico facilities. No injunction, no seizure. FDA took a corporate view of Baxter's cGMP problems with a Warning Letter addressed to its chairman, but this did not translate into an enforcement action. Baxter's Puerto Rico facilities were quickly re-inspected. Baxter was given opportunities to address FDA's concerns before FDA took a decision with respect to

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14:01:08 enforcement action or the lack thereof. The closeout letter was issued six months after the Warning Letter.

This contrasts with the treatment that Apotex received which is, by now, well familiar to the Tribunal. Apotex was placed on Import Alert. All products were banned for two years from Signet and Etobicoke. Both Etobicoke and Signet were on the Import Alert because FDA took a corporate approach to Apotex. FDA's re-inspection of these two facilities took two years to conclude.

Apotex was not given an opportunity to address FDA's concerns before it was placed on Import Alert, and the Import Alert was not lifted until June and July 2011. In like circumstances, Baxter received more favorable treatment than Apotex did.

I turn now to the U.S.'s justifications offered for Baxter's more favorable treatment.

Now, in its Counter-Memorial, the U.S. did not discuss any of Baxter's like circumstances except for the location of its facilities. The U.S. did not address Baxter's treatment either, other than the legal argument that we've already addressed the

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14:02:39 unavailability of import measures for products in U.S. territory.

In its Rejoinder, the U.S. raised two new arguments about Baxter. First, the U.S. insisted on the fact that Baxter recalled products. The products in question were a type of infusion pump. And you can see on the screen a press article referring to the recall of the infusion pump. Infusion pumps are medical devices. In other words, they have nothing to do with finished-drug cGMP violations. Baxter's recall of medical devices had nothing to do with the way the company handled its cGMP problems for finished pharmaceuticals.

Now, second, the U.S. claims that Baxter provided sufficient corrective actions. Here, the U.S. does not offer any supporting evidence. Nothing in the record suggestion that Baxter's corrective actions were sufficient, were timely, and fully implemented, as the U.S. claims in its Rejoinder as Paragraph 265. Now, in passing, the U.S. argues that it took Apotex more than a year to request re-inspection for the Etobicoke and Signet facilities.

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14:04:14 The U.S. focuses on Apotex's formal request for inspection dated August 27, 2010, and September 29, 2010, for each of Etobicoke and Signet. However, it should be recalled that Apotex had planned to request re-inspection much earlier than this, but was dissuaded from doing so by FDA itself. For instance, at the March 31, 2010, meeting with FDA, Apotex indicated that it wished to have the two facilities re-inspected. What you see on the screen is excerpts from Apotex's slides presented at that FDA meeting, which note that it wished to have a re-inspection conducted for each one of those facilities.

At the meeting however, FDA dissuaded Apotex from doing so by sounding a harsh note and making it clear--I'm quoting from the Desai Witness Statement--"making it clear that Apotex had to be fully ready before asking for re-inspection."

Finally, in a footnote, the U.S. also tries to downplay the significance of the 21 previous Warning Letters that Baxter received during the period 1997 to 2011. The U.S. argues that there was no

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14:05:53 Warning Letter for cGMP violations between 2001 and 2011. However, the U.S. does not dispute that 16 of the 21 Warning Letters issued to Baxter since 1997 were for cGMP violations, including four Warning Letters concerning finished pharmaceuticals.

Mr. President, Members of the Tribunal, this concludes our discussion of Baxter. I'd be happy to entertain any questions at this point if the Tribunal has any.

PRESIDENT VEEDER: No, thank you.

MR. LEGUM: One moment, please. A short pause to distribute the slides which have happily arrived.

(Pause.)

MS. DUFÊTRE: So I will turn to L. Perrigo, which is the last of the comparators selected by Apotex.

Perrigo Company is a pharmaceutical company incorporated in the United States. L. Perrigo Company is a wholly owned subsidiary of Perrigo Company. L. Perrigo is also incorporated in the United States. We noted in our Memorial that, like Apotex-U.S.,

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14:08:10 L. Perrigo Company and Perrigo Company's other U.S. subsidiaries sell finished drug products for human use, including those manufactured by Perrigo Company's subsidiaries in third countries.

Perrigo Company, L. Perrigo, and other subsidiaries of the group, own more than 100 Marketing Authorizations in the United States. In late 2009, early 2010, FDA inspected L. Perrigo facility in Allegan, Michigan. It found several cGMP deviations. In February 2010, L. Perrigo responded to the inspectional findings, and FDA reviewed the firm's response.

Following this review, FDA issued a Warning Letter to L. Perrigo in April of 2010. The Warning Letter noted, in particular, that certain Perrigo drugs on the U.S. market were contaminated, including with metal shavings. And this was noted in the Warning Letter itself, which is C-146. The Warning Letter also emphasized the chronic nature of L. Perrigo's cGMP problems. For instance, L. Perrigo had already, in the past, distributed mislabeled products that it had to recall. Altogether, FDA

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14:09:46 considered that L. Perrigo's prior Corrective Actions had failed. Again, this is in the Warning Letter, and the relevant excerpt is now on the screen.

FDA expressed concerns with L. Perrigo's ability to act proactively to ensure cGMP compliance. FDA called for global corrective actions at L. Perrigo. And yet, FDA took no enforcement action against Perrigo. After the Perrigo Warning Letter was issued in April 2010, FDA quickly re-inspected the Allegan facility in June 2010 and also in late March, 2011. FDA issued a Form 483 for the latter inspection.

On April 14, 2011, L. Perrigo announced that FDA had completed its re-inspection of the Allegan facility and concluded, effective immediately, that the firm had an acceptable regulatory status. And this information was stated in a press article, which is at R-193.

On May 9, 2011, FDA issued a closeout letter to Perrigo, which was about a year after the issuance of the Warning Letter.

I will quickly go through the "like

circumstances" that I'm sure the Tribunal almost knows by heart by then.

So other than the location of the facilities of L. Perrigo in the United States, the U.S. does not dispute that L. Perrigo was in like circumstances with Apotex. Like Apotex, Perrigo is an investor in the pharmaceutical industry. Like Apotex, Perrigo has investments in the U.S. in the form of Marketing Authorizations and enterprises which distribute in the U.S. product manufactured by subsidiaries of Perrigo. Perrigo is a leader on the U.S. generic market, and Perrigo competes with Apotex on that market.

In 2009-2010, FDA found serious cGMP violation at L. Perrigo's facility in Allegan, Michigan. Therefore, FDA's issued a Warning Letter in April 2010. FDA noted the repeat nature of the cGMP violations observed during this inspection. Therefore, L. Perrigo and Apotex were in like circumstances.

Besides the like circumstances, there are other circumstances specific to Perrigo which also ought to be taken into account since they shed light

on the treatment that was accorded by FDA to this company. Again, these circumstances are specific to L. Perrigo and are not like those of Apotex.

First, L. Perrigo's product created a health hazard. The Warning Letter noted several product defects, including the fact that L. Perrigo released ibuprofen tablets contaminated with metal shavings. And, again, this was noted in the Warning Letter issued to L. Perrigo in 2010. L. Perrigo also failed to thoroughly investigate possible foreign tablet contamination mixup. There was apparently a mixup between round tablets in a lot of oval ibuprofen caplets. L. Perrigo also released mislabeled products which later had to be recalled. This, again, was noted in the Warning Letter.

Second, L. Perrigo had opportunity to give several responses to FDA and to propose remediation actions. The Warning Letter notes that the FDA reviewed the firm's responses to the Form 483 before issuing the Warning Letter. And as the Tribunal may recall, the firm's answer to the Signet Form 483 was not reviewed before Apotex was placed on Import Alert.

The Warning Letter also notes--the Warning Letter to L. Perrigo also notes that the company had had several opportunities to correct problems since 2005 and had failed to do so. And the specific language is now on the slide.

Third, FDA was very prompt to re-inspect L. Perrigo, and FDA was also very prompt to clear L. Perrigo's compliance status and to issue a closeout letter. Again, the closeout letter came about a year after the Warning Letter was issued. L. Perrigo's chairman and CEO told the press that FDA treated the re-inspection of his firm as a priority and that FDA and L. Perrigo worked cooperatively to resolve the cGMP issues noted in the Warning Letter. Again, this was reported in a press article, which is at R-193.

After having looked at the circumstances, I will turn to treatment.

The U.S. does not dispute that FDA has taken no enforcement action against L. Perrigo. So I will repeat those same factors that we've seen before for all other comparators. FDA took no enforcement action against L. Perrigo. FDA did not ban from the market

any Perrigo products. L. Perrigo's facility was quickly re-inspected. FDA quickly cleared L. Perrigo's compliance status and issued a closeout letter. And L. Perrigo was given opportunities to address FDA's concerns before FDA took a decision with respect to any enforcement action or the lack thereof.

Now, in contrast, Apotex received less favorable treatment. As we all know, Apotex was placed on Import Alert. All of Apotex's products from Etobicoke and Signet were banned from the U.S. market for two years. FDA delayed the re-inspection of Etobicoke and Signet. As a result, the Import Alert was not lifted until June and July of 2011. And Apotex, more importantly, was not given any opportunity to address FDA's concerns before it was placed on Import Alert.

In these circumstances, L. Perrigo received more favorable treatment than Apotex.

I will now turn to the U.S. justifications made in the U.S. Rejoinder concerning Perrigo.

First, in the Counter-Memorial, the U.S. did not discuss L. Perrigo's like circumstances, again,

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other than the location of the facility; and similarly, the U.S. did not say a word about the treatment afforded to L. Perrigo. However, in its Rejoinder, the U.S. raised a new argument about L. Perrigo, and this is at Page 135 of the U.S. Rejoinder.

First, the U.S. suggests that Perrigo pledged timely corrective action, but the only evidence that the U.S. offers as support is the Warning Letter itself. If we look at the Warning Letter, FDA noted that L. Perrigo committed to conduct deviation investigations and to enter appropriate corrective actions and other similar type of corrective actions.

But however FDA also noted that L. Perrigo had already committed to corrective actions in the past, but failed to implement the proposed corrective actions. Again, this was noted in the Warning Letter.

The Warning Letter, therefore, offers no conclusive evidence that FDA considered that L. Perrigo's renewed commitments to Corrective Actions in 2010 were sufficient.

Second, the U.S. alleged that FDA withheld

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approval of Perrigo's request for Export Certificates. An Export Certificate is a document prepared by FDA containing information about a product's regulatory or market status. And I'm quoting here from Exhibit R-138. The U.S. introduced in the record Exhibit R-178, which is a letter from FDA to L. Perrigo that was sent sometime in 2010 and which denied the issuance of Export Certificates. But the exhibit does not establish that L. Perrigo was prevented at any point in time from selling its products in the United States. L. Perrigo was not prevented from doing so.

Apotex, therefore, fails to see how withholding approval of Export Certificates can compare with a total market ban on the U.S. market for products made at Etobicoke and Signet. On the facts of the case, the U.S. afforded more favorable treatment to Perrigo in like circumstances.

So this concludes our presentation on the selected comparators, and Apotex demonstrated that it received less favorable treatment than Teva, Sandoz, Hospira, Baxter, and L. Perrigo, which were all

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comparators in like circumstances. It follows that the United States has breached Articles 1102 and 1103 of the NAFTA.

MR. LEGUM: Mr. President, Members of the Tribunal, I will now begin our discussion of two comparators that were not put forward by Apotex as being apt comparators in this case, but rather, instead, were suggested by the United States as being comparators that the Tribunal should consider to be more apt than the comparators Apotex put forward.

I will discuss Ranbaxy, and then Ms. Dufêtre will come back to discuss Pfizer. Just pausing for a moment while the people can get their slides organized.

Ranbaxy, we submit, is not an apt comparator because it is not in like circumstances with Apotex. And even if we were to assume that it--like circumstances, for the sake of argument, Ranbaxy still received more favorable treatment than Apotex did. The U.S. arguments to the contrary do not withstand scrutiny.

Ranbaxy is not an apt comparator because its

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conduct went far beyond mere cGMP deviations. Ranbaxy submitted false data and information to FDA. It destroyed data it was required to preserve. It distributed drugs in the United States that it knew had failed test specifications.

In May of this year, Ranbaxy settled alleged civil violations of the False Claims Act with the United States Government, all 50 states, and the District of Columbia. As part of the settlement, Ranbaxy agreed to pay $500 million in damages.

The U.S. subsidiary of Ranbaxy also pleaded guilty to felony charges under the Food, Drug, and Cosmetic Act. Ranbaxy knowingly made material false statements to FDA, and it acknowledged this by pleading guilty to this fact. It is these actions that place Ranbaxy in circumstances unlike Apotex. And for these reasons, it is not an apt comparator.

Now, let me first quickly go through the Ranbaxy chronology.

In 2005, FDA received information about problems that suggested fraudulent manufacturer of drugs at two Ranbaxy facilities in India. And what

you have on the screen is a 2008 FDA media briefing that took place at the time FDA adopted the Import Alert, which helpfully provides a chronology up through that date. So I'll be referring to that quite a bit.

So in 2005, FDA received information that suggested fraudulent manufacture of drugs at these two facilities.

In February of 2006, FDA inspected Ranbaxy Dewas and Paonta Sahib facilities and found significant cGMP problems there.

In June of 2006, FDA issued a Warning Letter to Ranbaxy concerning its Paonta Sahib facility.

The violations cited in this Warning Letter concerned Ranbaxy's inadequate stability testing program where FDA found hundreds of unlabeled stability samples and no documentation concerning the storage and testing of these samples. The Warning Letter also indicates that FDA analyzed several batches of Ranbaxy product and found that the products had much lower potency than what Ranbaxy had reported them to have. FDA also uncovered abnormalities with

the markings on some of Ranbaxy's anti-retroviral drugs.

In August of 2006, Ranbaxy submitted a response to the Warning Letter that included corrections to the previously provided stability data. Now, at that time FDA did not take enforcement action against Ranbaxy. Quite the contrary, following the issuance of the 2006 Warning Letter, the FDA worked with Ranbaxy to facilitate corrections. This included several meetings with the company. Quoting again from the 2008 press release that's at--press discussion that's at C-331.

In January, February, and March 2008, FDA again inspected Ranbaxy's Paonta Sahib and Dewas facilities. FDA found significant cGMP violations at both locations.

In July of 2008, the U.S. Department of Justice filed a motion to enforce subpoenas against Ranbaxy in connection with a criminal investigation involving allegations of conspiracy, false statements, health care fraud, contract fraud, and causing the submission of false claims to federal health benefit

programs, in addition to violations of the Food, Drug, and Cosmetic Act.

In September 2008, FDA issued two Warning Letters following the inspections that had occurred in February and March in Dewas and Paonta Sahib. These Warning Letters cited continuing cGMP deficiencies at Ranbaxy.

Specifically, FDA found that employees who had indicated that they verified cleaning or manufacturing facilities were not even present at the facility on the days or times that the activities had occurred. And you have that on the screen from the 2008 Warning Letter.

As noted in both of the September 2008 Warning Letters, the Dewas and Paonta Sahib facilities were put on Import Alert as from that date. The Import Alert on Ranbaxy concerned 30 drugs. It made an exception, however, for one product called ganciclovir.

In February 2009, CDER determined that Ranbaxy had submitted untrue statements of material fact in its drug applications filed with FDA. This

finding was based on the stability samples taken during the June 2006 inspection and the firm's corrections submitted in August 2006. The corrections proved that Ranbaxy had submitted information in its applications that was false. Because of Ranbaxy's "pattern of systemic fraudulent conduct," FDA invoked the Application Integrity Policy against Ranbaxy on February 25, 2009.

Now, the Application Integrity Policy is invoked when a company's actions raise significant questions about the integrity of data in drug applications.

Mr. Edwin Rivera-Martinez in a statement emphasized the rarity of this action, stating that the AIP, the Application Integrity Policy, was last used "decades ago" during the generic drug scandal.

The fact--yes, please.

PRESIDENT VEEDER: My microphone is not working. The generic drug scandal, I don't know what that is. Is that something that we should know about?

MR. LEGUM: I believe it is well known to people who know about it. Unfortunately, I am not

among those people.

(Laughter.)

MR. LEGUM: I'm happy to get an answer for you.

PRESIDENT VEEDER: We'll raise it with someone else. Thank you. We'll come back to it later, as you wish.

MR. LEGUM: We'll come back to it later.

The fact that Ranbaxy was placed on Application Integrity Policy is but one demonstration of the seriousness of the issues at its facilities.

In 2011, an industry publication noted, "Clearly, Ranbaxy's problems are more serious than those of Apotex, as evidenced by its placement on FDA's Application Integrity Policy in February 2009." So for industry analysts, this was a determinative distinction at the time.

In January of 2012, Ranbaxy entered into Consent Decrees--into a Consent Decree of permanent injunction to address its violations of cGMPs and its data integrity issues. And I refer the Tribunal to Exhibit R-88 there.

FDA stated that the Consent Decree was taken as a result of Ranbaxy's continued violations of cGMP and its falsified information and its drug applications.

As I briefly mentioned in my introductory remarks, in May 2013, Ranbaxy U.S. pleaded guilty to felony charges and agreed to pay a criminal and civil fine of 500 billion U.S. dollars. Ranbaxy pleaded guilty to seven felony counts, including knowingly making material false statements to FDA.

Ranbaxy admitted that its criminal conduct went back to 2003. It also admitted that it made false, fictitious, and fraudulent statements in reports submitted to FDA in 2006 and 2007.

In September 2013, FDA added a third Ranbaxy facility, the Mohali facility in India, to the Import Alert. The Mohali facility has now joined the Paonta Sahib and Dewas facility, which remain on Import Alert today.

Having now reviewed this chronology, it is clear that Apotex is nothing like Ranbaxy. Apotex never committed any criminal offense. It did not have

to pay $500 million in civil and criminal fines. It was never placed on Application Integrity Policy. It did not falsify data in its drug applications. It did not make knowing material false statements to FDA. It did not knowingly and deliberately manufacture drugs that failed specifications, and it did not knowingly introduce defective drugs into U.S. interstate commerce with the intent to defraud or mislead.

In short, the extensive fraud committed by Ranbaxy renders it in circumstances unlike Apotex.

I turn now to treatment.

Now, Ranbaxy, for all other reasons I've identified, is plainly not in like circumstances with Apotex. But in any event, Ranbaxy was still afforded treatment more favorable than Apotex in important respects.

Ranbaxy was placed on Import Alert in 2008, two years after FDA issued the 2006 Warning Letter that found serious cGMP violations at the Paonta Sahib facility.

During that period of time, Ranbaxy had ample opportunity to propose corrective measures and to seek

the advice of Third-Party Experts, which it did. For instance, in February of 2006, Ranbaxy hired PAREXEL Consulting to help it return to cGMP compliance.

FDA worked with Ranbaxy during those two years to facilitate corrections, which included several meetings with the company. Ranbaxy provided at least three responses to FDA's inspectional observations before FDA issued the 2006 Warning Letter.

In August 2006, Ranbaxy submitted a lengthy response to the 2006 Warning Letter, which provided numerous corrections for data in its previously submitted applications. It submitted an additional response two months later.

In November 2006, FDA held a meeting with Ranbaxy to discuss the quality improvement program. FDA again met with Ranbaxy in June 2007 and later Ranbaxy submitted stability reports prepared by PAREXEL.

Ranbaxy provided additional reports in April 2008. After FDA inspected Ranbaxy's facilities again in 2008, Ranbaxy submitted responses to the 483s

14:36:08 issued to these two facilities. It was only after exchange of all this information that FDA determined to place Ranbaxy on Import Alert.

Apotex, on the other hand, was placed on Import Alert only two months after receiving its first Warning Letter ever and only 10 business days after the close of the Signet inspection, before it had an opportunity to provide a response to the Form 483 observations.

Now, the Etobicoke Warning Letter listed only two cGMP violations, the third being the late filing of FARs. One of these two had not previously been communicated to Apotex. So the response to that Warning Letter was the first opportunity Apotex had to address this concern.

Apotex submitted its response to the Etobicoke Warning Letter by letter dated July 17, 2009. However, FDA had not even completed its review of the firm's response when FDA decided to recommend the Import Alert against Apotex.

FDA allowed Ranbaxy to address its cGMP violations, hire third-party Experts, and exchange

14:37:36 multiple information with FDA before placing it on Import Alert. FDA reviewed the information and reports submitted by Ranbaxy's consultants before it made the decision to put it on Import Alert.

By contrast, FDA did not begin to Apotex's corrective actions and reports from third-party consultants until well after Apotex was placed on Import Alert.

So it was only until two years later, after the first Warning Letter, after FDA determined that Ranbaxy was not making progress, that it decided to place the two facilities on Import Alert.

If FDA had given Apotex the same treatment it gave to Ranbaxy to allow it two years to hire consultants and implement corrective actions, review the reports submitted by these consultants, FDA, in our submission, would never have taken the Import Alert against Apotex in the first place. After Apotex proposed and implemented its global corrective actions, FDA decided to lift the Import Alert.

I would also like to note that the severity of the Import Alert with respect to Apotex and Ranbaxy

14:38:59 was not the same. Ranbaxy was barred from importing around 30 drug products to the U.S., while Apotex was barred from importing its entire solid-drug dose portfolio manufactured for the U.S. market at Signet and Etobicoke.

As we've mentioned several times, this had a devastating effect on Apotex-U.S. It cut off 80 percent of the products that it depended on for its supply and had a very significant effect on Apotex's market position in the U.S. generic drug market.

Conversely, Ranbaxy's sales have, on the whole, increased from 2008 to 2012.

I turn now to the U.S.'s arguments advanced in its Rejoinder.

As a preliminary matter, the U.S. asserts that Ranbaxy is the comparator in most like circumstances with Apotex because it has a U.S. distribution subsidiary supplied by facilities outside the U.S. that received a Warning Letter and an Import Alert.

The record does not support the U.S.

First, the U.S. does not dispute that two

14:40:28 years elapsed between Ranbaxy's first Warning Letter in 2006 and its placement on Import Alert in 2008, while Apotex was put on Import Alert merely two months after it received its first ever Warning Letter. The U.S., however, claims that this is legally irrelevant to the like circumstances analysis. It is wrong. This fact is legally relevant to the treatment analysis as well.

Ranbaxy had two years to propose corrective actions. Apotex was placed on Import Alert before it could propose any corrective actions. Clearly there was a difference in the treatment these two firms received.

Second, the U.S. also argues that Warning Letters are "intended to give a firm or facility an opportunity, where possible, to take prompt corrective actions, but Warning Letters are not prerequisites to enforcement actions." Referring, now, to Paragraph 255 of the U.S. Rejoinder. As a matter of logic, it seems quite difficult for a firm to propose corrective actions to cGMP deviations when those deviations are not documented.

14:41:59 The U.S. may argue that such violations are documented in the Form 483 that may be issued at the close of an inspection. However, in the case of Etobicoke, one of the violations mentioned in the Warning Letter appeared there for the first time, meaning that it was not documented in the Form 483. And as the Tribunal will recall, Forms 483 represent inspectional observations that do not represent the position of the FDA.

In these circumstance, the first chance that Apotex had to address this issue was in its response to the Etobicoke Warning Letter submitted on July 17, 2009. With respect to Signet and the observations made on the Form 483 there, again, the Tribunal will now readily recall that it received that Form 483 on a Friday in August and had until a Monday in August to get back to FDA and propose corrective actions. This is not the same treatment.

The third argument that the U.S. puts forward in its Rejoinder is that it blames Apotex for "failing to mention that FDA had considered possible enforcement action against Etobicoke following the

14:43:31 2006 inspection."

Now, this assertion by the U.S.--excuse me. I'm referring to Paragraph 256 of the Rejoinder.

This assertion by the U.S. is difficult to understand. The first time Apotex saw the evidence that the U.S. relies upon concerning FDA's internal deliberations concerning the 2006 inspection was when the U.S. produced it with the U.S. Rejoinder.

The U.S. relied for this proposition on Exhibit R-141. This is the FACTS cover sheet for the 2006 Etobicoke inspection.

The acronym "FACTS" stands for "Field Accomplishments And Compliance Tracking System." It is the FDA's internal database centralizing data obtained by compliance officers concerning a firm or establishment. FACTS documents are not communicated to the inspected firm. Apotex did not receive this document before September of this year in this arbitration.

Now, as explained by Mr. Hay in the Memorial, Apotex submitted its response to FDA regarding the 2006 Etobicoke inspection in December 2006. FDA noted

14:45:06 that most of the responses appeared acceptable, but requested additional clarifications in April 2007.

Apotex submitted the requested information in May 2007, and in July of 2007, FDA formally notified Apotex that "the concerns and questions FDA had raised in its April 2007 request appear to be satisfactorily addressed." And I'm referring here to C-25.

So as far as Apotex was aware, there were no issues with the 2006 inspection. This was FDA's conclusion as well.

The fourth point that the U.S. makes is that it argues that Ranbaxy was not a felon at the time it was placed on Import Alert in 2008. It suggests that Ranbaxy was not yet a felon because it had not yet pled guilty or been placed on Application Integrity Policy.

The U.S. argument is that Ranbaxy could still be compared with Apotex because when it was placed on Import Alert, Ranbaxy had not yet admitted its criminal acts. This argument fails.

FDA decided--the timing of when FDA decided to take various enforcement actions against Ranbaxy

14:46:42 does not change the nature of Ranbaxy's conduct.

FDA suspected fraudulent manufacturing of drugs at Ranbaxy's facilities beginning in 2005. In 2006 FDA concluded that Ranbaxy was releasing products to market with much lower potency than reported. FDA also received corrections to prior stability data that called into question the accuracy of the information submitted by Ranbaxy.

All of the judicial and regulatory actions taken against Ranbaxy were based on conduct observed by FDA in 2006.

In July 2008, the U.S. Department of Justice, as I've already noted, had opened a criminal investigation against Ranbaxy for conspiracy, false statements, health care fraud, among other things.

Contrary to the U.S.'s suggestion, FDA knew full well that it was dealing with a felon when it placed Ranbaxy on Import Alert two months later in September 2008.

The fifth argument the U.S. makes is that Apotex had nine months from the Etobicoke inspection until FDA placed Apotex on Import Alert to take

corrective actions. I'm referring here to Paragraph 256 of the U.S. Rejoinder. This is not true.

As we have explained before, one of the violations in the Etobicoke Warning Letter was not indicated in the Form 483 handed out to Apotex at the close of the inspection. Concerning this specific violation, Apotex was only made aware of it in the Warning Letter received on July 25, 2009.

As Mr. Hay noted yesterday, another violation cited in that Warning Letter concerned timely submission of Field Alert Reports. As Mr. Hay also noted, Apotex did propose corrective actions to FDA on this topic, and FDA found that response to be adequate.

Moreover, for the third violation cited in that Etobicoke Warning Letter, that concerning electronic labeling, attaching labels in an electronic form, Apotex explained that to FDA in its response to the Warning Letter, and FDA eventually deemed Apotex's existing practice in that regard to be acceptable.

So, as the Tribunal will recall, FDA had not

even completed its review of Apotex's response to the Etobicoke Warning Letter before it recommended the Import Alert.

Clearly, on the facts of this case, Apotex's received less favorable treatment than Ranbaxy, and it was not in like circumstances with Ranbaxy. Ranbaxy had two years to propose numerous corrective actions and discuss those with FDA. Apotex and its proposed corrective actions were not even taken into account when FDA decided to place Apotex on Import Alert.

Mr. President, Members of the Tribunal, this concludes our review of Ranbaxy, the comparator proposed by the United States.

The last portion of our presentation concerns Pfizer. I think our current estimate is that it will take probably 20 minutes. So we can either do the coffee break now or we can do the coffee break later.

PRESIDENT VEEDER: I vote for the coffee break now. We come back at a quarter past 3:00.

MR. LEGUM: Thank you.

(Brief recess.)

PRESIDENT VEEDER: If we're all ready, let's

resume. It is now almost 3:20. We're not pressing you in any shape or form, but give us some idea of how we're going so far.

Are we going to finish tonight, or do we go into tomorrow morning?

MR. LEGUM: I think we will finish the prepared presentations tonight. What we would like to do, with the Tribunal's permission, is to come back tomorrow morning and then very briefly sum up and answer the Tribunal's questions that we haven't already answered.

PRESIDENT VEEDER: Of course. Take your own course, but that's fine by the Tribunal.

MR. LEGUM: Okay.

PRESIDENT VEEDER: So please continue.

MS. DUFÊTRE: I will now address Pfizer.

The U.S. in its Rejoinder introduced Pfizer as a new comparator. However, Pfizer is not in like circumstances with Apotex, and in any event, Pfizer received more favorable treatment than Apotex.

The U.S. theory on Pfizer is premised on the fact that two Pfizer licensing and supply partners,

namely Aurobindo and Claris, received Warning Letters for their Indian facilities, which were placed on Import Alert. And this is noted in the U.S. Rejoinder in Note 538.

In showing that Pfizer was not in like circumstances with Apotex, I will make three main points. First, Pfizer Injectables, because it is a division of Pfizer, is not comparable with the investment Apotex-U.S.

Second, Aurobindo and Claris are third-parties vis-à-vis Pfizer. They do not belong to the same corporate group.

And third, the quality issues found at Aurobindo's and Claris's Indian facilities are not comparable in nature with Apotex's cGMP deviations.

So, I start with Pfizer Injectables. Pfizer Injectables is not an investment of Pfizer eligible to serve as a comparator under Article 1102 because Pfizer Injectables does not qualify as an investment. Article 1102 requires a comparison of treatment with respect to "the establishment, acquisition, expansion, management, conduct, operation, and sale or other

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15:19:13 disposition of investments."
Pfizer Injectables does not qualify as an investment because it is a division of Pfizer. It is not a subsidiary.
Perhaps at this point I will say a quick word about Pfizer and its organization. Pfizer is an innovative pharmaceutical company that develops, manufactures, and distributes brand-name drugs such as Lipitor and Viagra. One of the biggest challenges faced by Pfizer is competition from generic pharmaceutical manufacturers. As a result Pfizer decided to enter the generic drug market.
Greenstone is a subsidiary of Pfizer which distributes in the United States solid oral-dose generic drugs. Pfizer Injectables, for its part, distributes sterile injectable products in the United States.
As is clear from the Pfizer Annual Report, Pfizer Injectables is a division of Pfizer, while Greenstone is a subsidiary. As a division of Pfizer, Pfizer Injectables is Pfizer. Under the NAFTA, an investor is one who seeks to make, is making, or has

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15:20:36 made an investment. The investor and the investment cannot be one and the same. Pfizer Injectables is not an investment of Pfizer. Pfizer is not an investor as concerns Pfizer Injectables.
Treatment concerning Pfizer Injectables is not eligible for comparison under the ordinary meaning of the Article 1102 because Pfizer Injectables does not qualify as an investment.
I will now turn to Aurobindo and Claris and show that they are not affiliated with Pfizer. Pfizer is not in like circumstances with Apotex because Aurobindo and Claris are third-parties independent and unrelated to the Pfizer group.
Aurobindo and Claris have concluded a Limited Supply Agreement with Pfizer. When selecting the comparators for this case, one of the criteria retained by Apotex was that "each comparator owns or controls, directly or indirectly, a business in the United States that distributes and markets its products, just like Apotex-U.S. does for Apotex."
And I'm quoting from the Memorial at Paragraph 446.

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15:22:05 The U.S. has tried to broaden the criterion to include a business model focusing on distributing products of competitors. According to the U.S., "like Apotex... Pfizer has U.S. subsidiaries that distribute and market Pfizer and third-party products in the United States."
And I'm quoting here from the Rejoinder at Paragraph 232.
However, third-Party products are not pertinent to identifying appropriate comparators. Aurobindo and Claris supply precisely such third-Party products to Pfizer. To use the U.S.'s own terms, Aurobindo and Claris are "Pfizer licensing and supply partners."
In fact, Pfizer and Aurobindo entered into a Licensing Agreement. And, similarly, Pfizer entered a License Agreement with Claris. Under these Licensing and Supply Agreements, the manufacturers--that is, Aurobindo and Claris--are responsible for manufacturing the products and they also hold the Marketing Authorizations associated with these products.

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15:23:37 Pfizer, for its part, is responsible for marketing and distributing the products supplied by Aurobindo and Claris. Aurobindo and Claris, therefore, supply some products to Pfizer for distribution in the United States. However, the suppliers remain Pfizer's competitors.
For example, in 2011, Pfizer sued Aurobindo for patent infringement when Aurobindo filed an application for Marketing Authorization for its generic drug Lipitor. There is no shared commitment between Pfizer and Aurobindo or Claris to long-term supply or development of a customer base in the United States. In fact, Pfizer terminated its deal with Claris just a few years after it began and after Claris was removed from Import Alert. Pfizer has no incentive to give value to the Marketing Authorizations of Aurobindo and Claris.
By contrast, Apotex is a vertically integrated group. As part of the Apotex Group, Apotex-Canada is the principal operating company which manufactures the Apotex drugs, and Apotex-U.S. is the distribution arm of Apotex in the United States.

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15:25:04 Apotex-Canada invests millions every year in identifying new business opportunities and opening up the U.S. generic drug market through patent litigation.

Apotex-Canada also invests millions in developing new generic drugs as well as preparing, filing, and maintaining the Marketing Authorizations with FDA. Apotex-U.S. collaborates in Apotex-Canada's decisions as to which products to develop for the U.S. market, when to launch the products, how to sell the products, and at what price. Their close collaboration ensures long-term supply and seemless delivery to Apotex-U.S.'s customers.

Prior to the Import Alert, as we've said many times in this hearing, Apotex-U.S. depended on Apotex-Canada for 80 percent of its supply. In the circumstances, Pfizer is not an apt comparator because its business model is not--is too different, too different from that of Apotex.

The main difference is that Apotex-U.S. distributes in the United States products supplied by Apotex-Canada; that is, an affiliated company within

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15:26:26 the same group of companies. In contrast, Aurobindo and Claris are not affiliated with Pfizer, and their relationship is--or in the case of Claris was--purely contractual.

I will now move to my second observation concerning Claris and Aurobindo's Indian facilities. Even if one were to assume that the relationship between Pfizer on the one hand and Aurobindo/Claris on the other hand could be compared with the relationship between Apotex-U.S. and Apotex-Canada, the fact remains that the Indian facilities at issue here are not in like circumstances with Etobicoke and Signet.

First, if we look at Claris, Claris's cGMP violations presented a clear health risk, unlike the violations observed at Etobicoke and Signet. Indeed, Claris's intravenous sterile bags were contaminated with fungus, as reported in several complaints from various customers including Pfizer. FDA observed that at least eight batches of two products were found contaminated with fungus.

During the 2010 inspection of Claris's Indian facility, FDA inspectors also observed the presence of

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15:27:59 liquid residue in the vessel labeled as clean that was later used to manufacture sterile drug products. Because Claris's drugs represented a risk to the public, FDA issued a Public Health Alert for three drugs manufactured by Claris in India and distributed in the United States by Pfizer, among others. And this Public Health Alert is at C-417.

By comparison, Apotex's drugs were never contaminated with fungus, and FDA never issued a Public Health Alert for Apotex products made at Etobicoke and Signet.

Now, if we look at Aurobindo, FDA inspected two units of Aurobindo's Indian facility. FDA inspected Unit 3, which is a facility which produces solid-dose products, and FDA also inspected Unit 6, which is a facility that manufactures cephalosporin active pharmaceutical ingredient, and cephalosporin finished drug products. Unit 3 was not placed on Import Alert. Only Unit 6 the cephalosporin facility, was.

Concerning the issues observed at Unit 6, the Warning Letter mainly concerned violations of the

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15:29:39 Food, Drug, and Cosmetic Act with respect to APIs, active pharmaceutical ingredients. And this is noted in the Aurobindo Warning Letter, which is at R-197.

Mr. Bradshaw and Mr. Johnson expressly excluded active pharmaceutical ingredients from their comparison. And this was noted in their First Expert Report at Paragraph 107. The reason is that manufacturing processes vary for APIs and finished drug products, and there are no cGMP regulations for the manufacture of API. Instead, FDA uses a guidance document for cGMPs for APIs, and this guidance document is in the record at CLA-625.

By way of summary, Pfizer is not an apt comparator because Pfizer Injectables does not qualify as an investment of Pfizer, Aurobindo and Claris are not manufacturing subsidiaries supplying other affiliates of the Pfizer group, and the nature of the cGMP violations at Aurobindo and Claris's Indian facilities is different in nature from the observations made at Etobicoke and Signet.

Now, moving on with treatment, in any event, Pfizer and Aurobindo/Claris, Pfizer received more

favorable treatment than Apotex. I will, here again, make three main observations. First, the U.S. refers to a Warning Letter sent to the Italian subsidiary of Pfizer--I briefly referred to that Warning Letter yesterday. The key point here is that eventually that Warning Letter had not been placed on Import Alert.

Second observation, the Import Alert observed--sorry, the Import Alert imposed on Aurobindo only affected five oral solid-dose products distributed in the United States by Pfizer.

And my third observation is that the Import Alerts imposed on Claris and Aurobindo affected only a few injectable products distributed in the United States by Pfizer.

So I will go into detail--into the detail of each of these three observations. I will be quick on the Wyeth Warning Letter, as I've already touched upon it yesterday. Again, the U.S. mentions this Warning Letter in the footnote to its Rejoinder. The footnote was dated March 27, 2013, and it concerned the Italian facility of Wyeth, which is a subsidiary of Pfizer.

The Warning Letter issued to Wyeth states

that the Catania facility reported out-of-specification endotoxin results in a product, and a portion of the contaminated batch was shipped to a contractor for distribution in the U.S. market.

As explained by FDA itself, endotoxin contamination is extremely dangerous for patients. Despite the seriousness of Wyeth's cGMP issues, the Catania facility has not been placed on Import Alert. Consequently, Pfizer, assuming that it could be in like circumstances with Apotex--which is not the case--Pfizer received better treatment than Apotex.

I move on to my second observation concerning the number of effected products. Even assuming that Pfizer's Greenstone and Aurobindo could be in like circumstances with Apotex-U.S. and Apotex-Canada--which is not the case--Pfizer and Aurobindo still received more favorable treatment than Apotex.

When Aurobindo's cephalosporin facility Unit 6 was placed on Import Alert, it did not substantially affect Greenstone's supply in the United States. As reported by Pfizer, the Aurobindo Import

Alert only impacted five solid-dose products manufactured by Aurobindo for Pfizer's Greenstone in the United States. And the name of the products, which I will not pronounce, are listed in Exhibit C-570, which is now on the screen.

So only five products were impacted by the Aurobindo Import Alert, while, in the case of Apotex, all products manufactured at Etobicoke and Signet were concerned by the Import Alert, with the exception of the deferiprone.

We've also said many times that Apotex-U.S. was deprived of 80 percent of its supply while Greenstone, in comparison, remained unaffected by the Import Alert imposed on Aurobindo. And this is shown, for instance, by the market ranking which shows that Greenstone remained in the same position or similarly same position during the time of the Aurobindo Import Alert.

In brief, the Import Alert imposed on Aurobindo was of little magnitude on Pfizer's Greenstone compared to the Import Alert imposed on Apotex. The effects on Greenstone and Apotex-U.S.

were not comparable in scope. It follows that, even if it were an apt comparator--which is not the case--Pfizer would still have received more favorable treatment than Apotex.

I will now say a brief word on the products that were affected by the Claris and Aurobindo products and--Import Alerts and distributed by Pfizer Injectables, but as I've noted in my introductory remarks, Pfizer Injectables is not an investment of Pfizer and, therefore, it doesn't serve as an apt comparator.

But for the sake of the argument, in any event, Claris manufactured only a limited number of products that were distributed in the United States by Pfizer. In fact, as reported in the press, the deal between Claris and Pfizer covered only 15 injectable products made by Claris. But the number of products that Pfizer distributed in the United States is even smaller than that. Pfizer only distributed three products made by Claris in the United States.

After checking the FDA drug labels for all ANDAs held by Claris and listed in the Orange Book, it

15:37:20 turns out that Pfizer had labels only for three products manufactured by Claris, and, therefore, only three products were distributed in the United States by Pfizer.

Okay. So there were three products manufactured by Claris and distributed by Pfizer in the United States, and by way of example, what you now see on the screen is the label for one of those products. And it clearly shows that Claris Life Science Limited manufacture, analysis, et cetera. So under "Manufacturer," the name of Claris is mentioned. It will be clearer looking at the exhibit in the record.

The other labels are also in the record, so besides this Exhibit 562, the two other labels are Exhibit C-563 and C-564. And all three labels mention that the products are manufactured by Claris. In other words, the Claris Import Alert only affected three products distributed into the United States by Pfizer Injectables.

Similarly, if we look at the Aurobindo Import Alert, the Import Alert only affected four products

15:39:00 distributed in the United States by Pfizer Injectables, and this was reported in a press article published in Bloomberg on March 4, 2011.

As a result, the Import Alerts imposed on Claris and Aurobindo did not affect Pfizer Injectables in the same way and magnitude as the Import Alert affected Apotex-U.S.

The Import Alert imposed on Claris and Aurobindo only impacted a total of seven products distributed by Pfizer Injectables in the United States. By way of comparison, the Import Alert banned from the U.S. market all products made at Etobicoke and Signet.

By way of conclusion, Pfizer is not in like circumstances with Apotex, and, in any event, even if it were, it received more favorable treatment than Apotex.

So, we have shown that on this record, the five selected comparators were all in like circumstances with Apotex and received more favorable treatment than Apotex. It follows that the United States breached both Articles 1102 and 1103 of the

15:40:19 NAFTA.

And this concludes our presentation on the comparators.

PRESIDENT VEEDER: Just before you leave us, could you help us with the references to the pleadings in regard to Pfizer? You referred us to the Rejoinder Paragraph 232. But where was it expressly mentioned in the Memorial and the Counter-Memorial and the Reply?

MS. DUFÊTRE: Pfizer?

PRESIDENT VEEDER: It wasn't?

MS. DUFÊTRE: It was raised for the first time in the U.S. Rejoinder. This was the subject of our application to exclude, which has been denied.

PRESIDENT VEEDER: Of course it was. Thank you.

MR. LEGUM: Mr. President, we're going to have a change of personnel sitting in the chair to my right. And so while that takes place, I can say that--thanks.

ARBITRATOR ROWLEY: We'll close our eyes.

MR. LEGUM: No need to.

15:41:14 The generic drug scandal apparently was one that took place in the 1980s, at the beginning of the generic drug industry in the U.S., when a company called Bolar was found by federal investigators to be manufacturing products using unapproved formulas and manufacturing processes. And it resulted in a guilty plea by someone named Robert Shulman in November 1991, conspiring to defraud the Food and Drug Administration, among other charges.

PRESIDENT VEEDER: Thank you very much for that.

Do you want longer to switch around? Do you want five minutes?

MS. WEIL: May I have one more minute, please?

PRESIDENT VEEDER: Of course you may. You may have more than one minute.

(Pause)

PRESIDENT VEEDER: Okay. We'll resume.

MR. LEGUM: Thank you.

Mr. President, Members of the Tribunal, I will now begin our presentation on Article 1105 of the

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15:43:33 NAFTA and the Effective Means provision of the U.S.-Jamaica Bilateral Investment Treaty.

I will show that the Import Alert failed to accord Apotex the basic due process required under international law. I will begin by briefly discussing what Article 1105 requires and addressing the argument that the United States raised concerning limitation of Article 1105 to investors--excuse me, investments in its Rejoinder.

I will then discuss the requirement under customary international law that due process protections be provided in administrative decision making.

My colleague, Kristen Weil, will then demonstrate that the U.S., in putting Apotex on Import Alert, failed to provide any due process and safeguard. She will show that Apotex was not afforded an impartial administrative authority, notice, or adequate information on the proceedings so that Apotex could present a defense or an opportunity to contest the evidence against it.

I will show that none of the four professed

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15:44:51 remedies--after her presentation, I will show that none of the four professed remedies that the U.S. now puts forward could have provided available or effective relief. I will show that, contrary to the U.S.'s current position, none of the actors mentioned any of these alleged remedies at the time, and FDA maintained that the only way Apotex could seek to have the Import Alert lifted was through successful re-inspection of its facilities.

Finally, I will show that the same facts that establish a breach of NAFTA Article 1105 also establish a breach of provisions of the U.S.-Jamaica Investment Treaty which applies here under the MFN Clause in Article 1103 of the NAFTA.

I begin with Article 1105(1). That paragraph provides "Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."

Article 1105 requires that investments made by investors of another NAFTA Party be given the Standard of Treatment required under international

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15:46:17 law. This minimum standard is referenced in the Note of Interpretation of the Free Trade Commission of the NAFTA issued in 2001. The disputing Parties agree on this point and also agree that the minimum standard requires that basic due process be provided to aliens.

Now, in its Rejoinder, the U.S. makes a new argument based on the text of Article 1105(1). It contends that Apotex has failed to State a claim under Article 1105 because Apotex supposedly challenges treatment accorded to it as an investor rather than treatment accorded to Apotex's investments. This argument is without merit for several reasons.

First, it mischaracterizes Apotex's position. Apotex's Memorial plainly alleges breaches, including of Article 1105(1), for treatment accorded to its investments, notably to Apotex-U.S.

For example, the Memorial in Paragraph 470, which you now see on the screen, makes clear that Apotex's claim addresses a breach of fundamental due process with respect to Apotex Holdings and Apotex-Canada's investments in the United States.

Second, the U.S. argument is, in any event,

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15:47:45 irreconcilable with the NAFTA's text, context, and object and purpose. The term "investment" is defined in Paragraphs (a) through (h) of Article 1139. It is defined to include eight different elements. Of these, only the first one, an enterprise, has a separate legal personality. The remainder, ranging from debt and equity securities to real estate to various kinds of interests, consists exclusively of things, inanimate and often intangible objects.

Now, all Parties agree that the Article 1105(1) requirement of fair and equitable treatment includes an obligation to accord basic due process. But things cannot generally be a Party to proceedings, only persons, whether natural or legal, can be.

While a court can deny justice to a Shareholder, in proceedings concerning equity securities, a court cannot deny justice to the securities. Securities cannot bring an action in justice. They have no entitlement to it, as such. Similarly, while a Shareholder may well have legitimate expectations as concerns the treatment of

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her shares, the shares themselves can have no expectations. They are inanimate.

The U.S. argument would permit a State to deny fair and equitable treatment to investors as concerns their investments except where an enterprise is the subject of a denial. A Mexican court could, for example, arbitrarily strip a U.S. investor of its shares and no NAFTA claim would lie because justice was denied to the investor rather than to the shares. This simply cannot be right.

NAFTA and other jurisprudence, in fact, confirm that this is not right. In Cargill versus Mexico, the Tribunal found a breach of the Minimum Standard of Treatment with respect to the investor, Cargill itself. In that case, the Tribunal would--in that case, the Tribunal found that the institution by Mexico of a permit requirement for a few high fructose corn syrup producers was, in reality, an attempt to alter U.S. trade policy in the sector. It found that such conduct was manifestly unfair and contrary to the standard set out in NAFTA Article 1105(1).

As this Tribunal can see from the text on the

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screen, the Cargill Tribunal found that Mexico had failed to accord to the Claimant the treatment under international law required by Article 1105(1).

This position also finds support in contexts outside of the NAFTA. For example, in Bahloul versus Tajikistan, the Tribunal concluded that the fair and equitable treatment obligation in Article 10(1) of the Energy Charter Treaty protects not only investments, but also investors.

In that Award, the Tribunal noted as follows, and I'll quote the language because it's fairly pertinent, "Article 10(1) ECT read literally protects only the investment and the not the investor. Vivalo, being a Bahamian company, would not even constitute an investment protected under the ECT. However, this Tribunal considers that it would be contrary to the object and purpose of the ECT to allow a Contracting Party to deny due process to a company owned by an ECT national.

"In the case at hand, this is even more conclusive, since the Shares in the joint ventures held by that company--being the object of the Court

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proceedings--constitute investments indirectly owned by the investor."

Similar positions have been adopted by other Tribunals, notably the Plama versus Bulgaria and Siemens versus Argentina Tribunals. The references are on the screen with the quote of the relevant language from the Plama case.

In short, Article 1105(1) must be read to encompass a denial of fair and equitable treatment to an investor as concerns its investment. If it were not so read, all of the investments contemplated by Article 1139 of the NAFTA would not be covered by this Article, save the first one, which is an enterprise.

There is no merit to the new U.S. argument that Article 1105(1) does not encompass a denial of due process to an investor with respect to its investment.

ARBITRATOR CROOK: I do have a lot of sympathy for the argument you're making, that the words can't possibly mean what they say. But on the other hand, they do say what they say. And so I'm just trying to think through in terms of, in Vienna

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Convention terms, how you get from here to there.

I mean, yes, I hear the object and purpose, but words are to be construed in accordance with their ordinary meaning and object and purpose. And ordinary meaning is that "investors" doesn't mean "investments." I don't have a position here, but I'd be interested to see in sort of Vienna Convention terms how you get there.

MR. LEGUM: Well, I think that the answer lies in the verb in Article 1105(1). "Accord treatment to investments of investors."

In according treatment to investments in this context, given the obligations that are set out in Article 1105(1), an according of treatment with respect to an investment, a denial of due process with respect to an investment, must be read to encompass the situation where the investor that owns the investment is a Party to the proceedings as long as the proceedings, obviously, concern the investment.

ARBITRATOR CROOK: I don't want to belabor it, but it's an interesting conundrum.

MR. LEGUM: Shall I proceed to my next point?

15:55:24 And I'll reflect upon the question overnight and, perhaps, come back with some additional observations.

ARBITRATOR CROOK: I certainly take the point that sort of various Tribunals have decided along the lines you've suggested, and certainly for reasons of logic there's--you know, the argument you make is a quite logical one. But on the other hand, it's not what the words say.

MR. LEGUM: Mr. President.

PRESIDENT VEEDER: Just one question. You cited Cargill. Are there any other NAFTA cases, Decisions or Awards on this very point?

MR. LEGUM: I do not believe so.

ARBITRATOR CROOK: As you reflect on it, would you--you know Cargill better than I, I'm sure, but my recollection there is that the Measure did affect the enterprise. And you can tell me in due course whether that's right not.

MR. LEGUM: It did. It's analogous to the situation here in that the enterprise relied on products sold to it by the parent company in the U.S., and the import permit prevented--requirement prevented

15:56:36 those supplies from reaching it. And the denial--but I think it was--the reason why the Cargill Tribunal was confronted with this, I believe, was because the import requirement was one that the U.S. company had to fulfill in order to be able to send the products to its subsidiary in Mexico.

But anyway, I'll take it up--

ARBITRATOR CROOK: It's a fact question. They did whatever they did. I remember it a little differently, but the facts are whatever they are.

MR. LEGUM: Indeed.

I come now to the applicable standard of treatment under customary international law, and Article 1105(1).

The relevant standard here, Apotex submits, is reflected in Section 181 of the 1965 Restatement Second of the Foreign Relations Law of the United States.

Section 181 provides--and I'll actually read the language, although I believe that the Tribunal is familiar with it. It provides that: "A trial or other proceeding to determine the rights or liabilities of

15:57:46 an alien must be fair. In determining whether the proceeding is fair, it is relevant to consider, among other factors, whether--it is relevant to consider, among other factors, whether the alien has had the benefit of an impartial... Administrative Tribunal, adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense, a reasonable opportunity to contest evidence against him, reasonable opportunity to obtain and present Witnesses and evidence in his own behalf"...

Now, the American Law Institute recognized that these requirements are part of the International Standard of Justice.

The Restatement observes, in Section 165, that these requirements reflect the "applicable principles of international law" as well as "analogous principles of justice generally recognized by States that have reasonably developed legal systems."

The standards set forth in the Restatement were considered to reflect established customary international law as of 1965. The record notably

15:59:15 contains no authority or form of State practice suggesting a dilution of these principles in the intervening half century.

To the contrary, the record shows increasing international recognition by States of the rule of law and its universality. These requirements reflect long-established customary international law.

Now, I'd like to pause for a moment on the standard articulated by the Restatement. Notably, in the chapeau of the provision, the Restatement makes clear that the list of due process protections it identifies are factors that are relevant to consider. The Restatement does not suggest that these are elements that must be present in every case. To the contrary, the Restatement makes clear in Comment B that "they are not all required in all types of proceedings."

But in no circumstance does this mean that no due process must be provided. The commentary to the Restatement notes that under customary international law, the absence of any one of the factors could be determinative of whether procedural fairness was

denied.

And I'm referring there to Comment B again.

The second point I would like to make concerns the list of due process protections. Section 181 includes eight protections in this list.

Apotex, and in its submissions, has focused on four of these. It does so not because it is cherry picking, as the United States suggests; rather, it focuses on these four because the other four are not pertinent to the facts of this case. The missing four deal with interpretation and translation into foreign languages, an opportunity to communicate with a representative of the alien's government, an opportunity to consult with counsel, and reasonable dispatch by the authorities in reaching a determining.

While disputing some aspects of the Restatement's approach, the U.S. does not appear seriously to challenge its essence.

In its Rejoinder, for example, the U.S. refers to U.S. Supreme Court decisions taking a flexible approach to due process requirements similar to that of Restatement Section 181. And you see the

text from the U.S. Rejoinder at Paragraph 299 on the screen.

The U.S. does not deny that Tribunals, in assessing whether basic due process has been accorded, should appropriately consider factors such as the partiality of the deciding authority, the information provided concerning the proceedings, and whether the alien had a reasonable opportunity to contest evidence and put on its own case.

It would be difficult for the U.S. to take such a position because it is both eminently sensible as well as established in international law that these are pertinent factors to consider.

Instead, the principal stated disagreement the U.S. appears to have with the Restatement approach is that the Restatement clearly requires some level of due process in all administrative decision making, whether in deciding on a permit application or in a formal adjudication.

Now, I will come to this in a moment, but before doing so, I note two unstated reasons why the U.S. does not like the Restatement's formulation.

First, consideration of the four factors pertinent to the Import Alert shows that the U.S. provided Apotex not a single one of these factors. Apotex had no access to an impartial adjudicative--administrative authority, no adequate information about the nature of the proceedings, no opportunity to contest evidence against it, and no reasonable opportunity to present its position. The Import Alert adopted against Apotex comes up zero for four on the pertinent Restatement factors. While the U.S. doesn't dispute the pertinence of these factors, the score card is not one that supports its position.

Second, while the Restatement, as already noted, does not require all procedural safeguards to be provided in every context, it does provide clear guidance on how much process is due. It states in Comment B--and that text is now on the screen--that the extent to which the specific safeguards indicated in this section may be requisite for a fair trial or other proceeding will depend primarily on, one, the seriousness of the consequences to the alien, and, two, the extent to which the exercise of

administrative discretion is reasonably involved in the determination of the case.

The seriousness of the consequences to Apotex is well documented in this record. The Import Alert was devastating, and FDA knew it would be. The importance of this factor alone makes clear that substantial process was due Apotex and none was accorded. This is the second unstated reason why the U.S. is uncomfortable with the Restatement.

As noted, the U.S. argues that the Restatement factors do not apply at all to administrative decision making. The U.S. argues, without basis, that while due process is required if a State elects to afford administrative adjudication, no due process is required for administrative decision making under international law if a State does not provide adjudicative procedures. I'm referring here to the Rejoinder at Paragraphs 318 and 319.

Apotex addressed at some length in its submissions the U.S.'s two-tiered approach to due process. I will not repeat all of those arguments here, but I will recall some of the main points.

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16:06:29 First, the Restatement and State practice establishes that the due process protections extend to administrative decisions and is not limited to adjudication. There is no support for the U.S. position in the Restatement or in its commentary. The text of the Restatement refers to a trial or other proceeding and addresses, as decision makers, the Tribunal or administrative authority.

This is second 181 Paragraphs (a) and (h).

The commentary to the Restatement makes clear that a proceeding, in its terms, is broader than adjudication. The commentary includes as examples issuance or revocation of a license, granting or denying a zoning ordinance variance, criminal parole, exercise of executive clemency, waiver of penalty for overdue taxes, granting a permit to travel in restricted areas, and granting a public utility franchise. These are classic examples of administrative decision making. The American Law Institute found in 1965 that customary international law extended to these decisions.

Second, Apotex demonstrated in the Memorial

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16:08:00 and the Reply the considerable State practice supporting the Restatement's position that some level of due process is required in administrative proceedings. I refer the Tribunal to Pages 137-143 of the Memorial, and Pages 133-138 of the Reply.

These show that the laws of, among many others, France, Italy, Sweden, Denmark, Germany, Spain, Peru, Argentina, Costa Rica, Columbia, Japan, and South Korea, Greece, and Portugal, all contain principles of fair administrative proceedings. I will not repeat that showing here, but will refer the Tribunal to the submissions I've already referenced.

Moreover, NAFTA Chapter 18 in general and Article 1804 in particular require basic due process in administrative proceedings applying Measures respecting any matter covered by the NAFTA to particular persons, goods, or services or another Party in specific circumstances.

At the time of the adoption of this provision, Canada noted that this chapter reflected "basic procedures necessary to meet the requirements of due process and natural justice for all matters

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16:09:41 covered by the Agreement."

Again, basic due process protections like those in Chapter 18 were understood by the NAFTA Parties as natural justice applicable to all.

The U.S. also challenges Apotex's reliance on the Restatement by asserting that the Restatement factors need not be afforded before taking action. And I refer the Tribunal, again, to the Rejoinder at Paragraphs 318 and 319.

Now, as an initial matter, Apotex has never argued that customary international law invariably requires due process before a State may permissibly take an administrative decision with severe impact on an alien. Rather, Apotex's position is and always has been that the amount and timing of the due process depends on the context. This is what the Restatement says.

Apotex agrees that under some circumstances--notably, those where there is evidence of imminent harm--ex post process is acceptable. The argument that the U.S. attacks is not one that Apotex has made. The U.S. knocks down a straw man.

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16:11:12 Moreover, the U.S. asserted in its Rejoinder for the first time that Apotex failed "to identify a single State anywhere in the world that recognizes Apotex's proposed rule of customary international law," as concerns the importation of drugs. My reference is to the Rejoinder, Paragraph 285.

While Apotex disagrees that State practice at such a microscopic level is required, we note that the U.S. is incorrect. As we noted in our pleadings, France generally requires due process safeguards to be afforded when administrative decisions are made. With respect to the import of medical products in particular, we refer to the new Legal Authorities submitted as CLA-634 and 635.

Now, I will not develop this point further other than to note that these provisions mandate that, with the exception of an emergency situation, the natural or legal person concerned shall be put in a position to present its observations before the adoption of the suspension Measures. Of course, in order to be able to present observations, a person must have been duly notified of the adoption of the

Measures.

ARBITRATOR CROOK: I was sort of curious how that was going to come up. I mean, is the proposition that this is State practice relevant to proof of a customary rule of international law? If that's not the claim, what do we learn from the French statute?

MR. LEGUM: Well, first of all, our proposition is that the State practice reflects the general principles that are set out in the Restatement. And it would be, I think, highly unusual for an international Tribunal to require State practice of, for example--of something like due process at a level as microscopic as in a specific type of proceeding.

So it is not our position that that is something that is a showing that needs to be made. We're putting this in the record simply as a response to the U.S.'s argument, which seems to draw some significance to the fact that, although the four procedural safeguards that we rely upon are well established in customary international law, that the record does not have any instance of a single State

that has afforded due process under its laws with respect to this particular type of Measure. So it's simply a response to the U.S. argument.

I feel confident that there is much more State practice on this topic out there, but it would require quite a bit of resources to collect it all and present it.

In its Rejoinder, the U.S. also emphasizes that FDA enjoys discretion under national law in its enforcement decisions. Apotex agrees that under the Restatement the extent to which the exercise of administrative discretion is reasonably involved is a factor in assessing what degree of process is due.

The Tribunal will recall the slide that I showed earlier of Comment B to Section 181. And, indeed, the extent to which the exercise of administrative discretion is reasonably involved in the determination of the case is one of the two factors that is to be considered in deciding how much due process is required.

The other factor, however, is the severity of the consequences to the alien. As already noted, in

light of the severe impact the Import Alert had on Apotex, as FDA knew it would, it is evident in this case that substantial due process was required.

As we've demonstrated in our submissions, international case law supports our position that due process is required in administrative proceedings even when administrative discretion is required.

Cases such as international Thunderbird investment v. Mexico, Genin versus Estonia, and GAMI Investments versus Mexico do not support the U.S.'s assertion that FDA's actions should be accorded deference. Instead, these cases recognize the importance of the type of procedural safeguards enumerated in the Restatement.

First, we remind the Tribunal that, as we discussed at Page 149 of our Reply, GAMI Investments did not address procedural due process at all. It dealt with claims that the Mexican Government had failed to implement certain provisions of its own law. It, therefore, is inapposite to this discussion.

Nor does International Thunderbird support the U.S. The U.S. is correct that in that case, the

Tribunal concluded that Thunderbird had received due process, despite the fact that the administrative authority in question initially closed Thunderbird's gaming facilities without a prior hearing. However, the Authority Then recognized that the official Closure Order was irregular and decided itself to lift the Order. Then, after an administrative hearing, during which Thunderbird was able to present evidence, the Authority issued a new Administrative Order closing the facilities.

Thunderbird challenged the second Closure Order before a NAFTA Tribunal, but the Tribunal rejected the challenge. And the relevant text is on the screen. In doing so, the Tribunal noted that Thunderbird was given a full opportunity to be heard and to present evidence at the administrative hearing, that the Administrative Order was adequately detailed and reasoned, and that the proceedings were subject to judicial review before the Mexican courts.

By contrast, none of procedural safeguards considered by the Thunderbird Tribunal was afforded in this case. Apotex did not have a full opportunity to

16:18:08 be heard and to present evidence, it did not receive adequately detailed and reasoned explanations for why the Import Alert was imposed, and Apotex had no right to a judicial review of FDA's decision as FDA routinely takes the position in U.S. courts that an Import Alert is not judicially reviewable.

In another case, Genin versus Estonia, the Tribunal expressed deep discomfort with the Bank of Estonia's failure to provide the types of procedural safeguards enumerated in the Restatement. The Tribunal was troubled that the bank failed to provide advance notice or an opportunity to be heard to the Claimants' company before revoking its banking license, but ultimately concluded, based on a specific set of facts that are quite distinct from those here, that there was no due process violation.

Now, the U.S. does not come to grips with the key factual distinction between this case and Genin.

Whereas Genin obfuscated even the most basic facts of his business, including the address, who the Shareholders were, and the ownership of the shares, Apotex has cooperated with FDA and complied with U.S.

16:19:31 regulatory schemes by opening its facility to inspections, maintaining open dialogue with FDA, complying with pre- and post-approval reporting obligations, and taking proactive steps to alleviate FDA's concerns, such as initiating a voluntary recall.

Whereas, Genin knowingly chose to invest in a place where emerging State institutions were responsible for overseeing and regulating areas of activity previously unknown, and the circumstances of political and economic transition prevailing in Estonia at the time justified heightened scrutiny of the banking sector, the U.S. offers a highly developed legal and Regulatory Framework that provides thorough oversight.

Moreover, while due process in Genin would not have impacted the result had it been accorded, the record in this case demonstrates that if Apotex had been afforded the due process protections available to investments supplied by plants in the U.S., FDA would never have cut off its supply of products.

The U.S. suggests that this matter is similar to Genin and that Apotex has conceded that the

16:20:56 Etobicoke and Signet facilities failed to comply with cGMP. Not so. From the very outset of this arbitration, Apotex made clear that--and I'm quoting the Request for Arbitration--"Apotex-Canada rejected FDA's suggestion that its facilities were not compliant with cGMP." This is the Request for Arbitration, Paragraph 43.

Rather, Apotex has said, as a legal matter, that the claims of less favorable treatment and failure to accord due process asserted in this arbitration do not depend on the correctness of FDA's findings. Whether correct or not, FDA found cGMP violations as to Apotex and as to the comparators. But only Apotex-U.S.'s supply chain was severed for two years.

Whether those findings are correct or not, FDA afforded Apotex no process in imposing the Import Alert. The findings are not in dispute in this case, but only because Apotex's claims do not depend upon the correctness of FDA's decisions. There is no merit either to the U.S. assertion of a concession on Apotex's part or its reliance on the Genin case.

16:22:17 Mr. President, Members of the Tribunal, that concludes my review of the applicable international standard of due process applicable here. I would now--unless the Tribunal has a question--turn the floor over to Ms. Weil to apply those standards to the facts of this case.

PRESIDENT VEEDER: Give me one second. Please continue.

MS. WEIL: Mr. President, Members of the Tribunal, I will now demonstrate that Apotex was denied the basic due process required by international law.

I begin by noting that the record in this case establishes not only a failure to accord basic due process, but also that that failure resulted in the Import Alert. The record shows that if the U.S. had afforded Apotex due process, the Import Alert would never have been imposed.

The record shows that FDA took action before completing review of Apotex's responses and based on faulty information or misunderstandings. Had due process been afforded, Apotex could have clarified

those misunderstandings, and the Import Alert never would have been imposed.

Experts Ron Johnson and Sheldon Bradshaw concurred with this assessment in their First Report. They concluded that had Apotex been afforded the due process rights that FDA regularly provides to U.S. companies, FDA would not have prevented Apotex products from being sold in the U.S.

The process by which FDA enjoins a U.S. company from selling products in the U.S. accords vastly more due process than that was afforded Apotex.

First, FDA would provide multiple opportunities to remediate cGMP violations before it pursued enforcement action. This includes the opportunity to remediate cGMP violations noted as 483 observations, and in Warning Letters, as well as other exchanges with the company.

If those opportunities proved fruitless, numerous offices within FDA and the Department of Justice would review and assess the facts and evaluate whether to recommend enforcement action. If the Department of Justice concurred, it would then file

suit in federal court. Following briefing from the Parties in which they could present evidence in support of their positions, the independent federal judge would decide whether an injunction was proper.

Thus, to pursue enforcement action against a domestic facility, numerous offices within FDA and other Executive Branch agencies would have to be involved in the process. And their decision would have to be approved by an independent authority; in this case, a federal judge.

The U.S.'s Expert testimony from William Vodra supports this assertion. Mr. Vodra testified that there are "profound differences" in FDA's authority with respect to domestic and foreign facilities and in the standards that are applied to each.

For example, Mr. Vodra testified that FDA may take action against drugs manufactured at domestic facilities upon proof of adulteration. Whereas, FDA may act against foreign manufacturers upon the mere appearance of adulteration. Certainly, if Apotex had received the treatment and procedural protections

afforded a domestic company, it would not have been placed on Import Alert.

This, as noted, is what Mr. Bradshaw and Johnson concluded. That conclusion has not been disputed by the U.S.

The record, Apotex submits, shows that due process would have made a difference in this case, had it been afforded. Due process, however, was not afforded Apotex. The U.S. failed to provide any of the four pertinent procedural safeguards listed in the Restatement Section 181. I will address each of these safeguards, in turn.

First, CDER was not an impartial authority. The U.S. contends that there is impartiality because multiple offices participate in the process by which FDA makes enforcement decisions. According to the U.S., CDER reviews on-site inspectors' findings and makes a recommendation which DIOP then reviews, and the Office of Chief Counsel advises on legal considerations. However, the U.S.'s contention is unavailing.

As an initial matter, the U.S.'s own Witness,

Dr. Carmelo Rosa, acknowledges that FDA changed its Warning Letter process in the middle of 2009 to exclude from its review the Office of the General Counsel, one of the offices that the U.S. argued adds impartiality to this process. There is no evidence that the Office of General Counsel was consulted on the Apotex Import Alert.

But even if different offices may participate, it is nonetheless the same agency that makes and reviews decisions which renders the process flawed. Apotex's Experts described how DIOP generally rubber stamps CDER's recommendations and does not exercise independent review and judgment.

The evidence in this case supports that testimony and demonstrates that DIOP's role in issuing the Import Alert to Apotex consisted merely of implementing CDER's recommendation rather than independently evaluating it.

First, the only information that DIOP received from CDER was the 2 1/2-page memorandum requesting that the Import Alert be imposed against Apotex. This memorandum was prepared on August 20,

2009, by Rick Friedman, the director of CDER. DIOP had no access to any supporting documents.

Second, that memorandum was transmitted to DIOP on August 25, 2009. The day before, however, on August 24, 2009, a CDER officer told an industry gathering that "Next week you'll be reading about how FDA has placed a company on Import Alert only seven business days after the conclusion of a foreign inspection."

Now, let me pause here.

CDER was so confident in the outcome that they told the world that the Import Alert would be adopted even before they sent the request to DIOP.

Their, after Dr. Rosa e-mailed DIOP to inquire about the status of the Import Alert, DIOP approved it within 30 minutes. Even this delay struck some in FDA as too long.

Mr. Friedman asked in an e-mail, which you see here, dated August 28, 2009, why OIP took four extra days to actually post the Alert rather than post it on the very same day that CDER recommended that DIOP adopt the Import Alert.

This demonstrates that DIOP did not independently review the recommendation to issue the Import Alert or any of the underlying facts.

With respect to the Signet inspection, FDA's review did not involve multiple offices. Inspectors sent their on-site observations straight to CDER without first sending them to the district for review, contrary to normal procedure. Thus, Apotex's' individual experience differs from the general policy that the U.S. has said FDA follows. The lack of impartiality in process is evident in how rushed the decision to adopt the Import Alert was.

The Signet inspection ended Friday, August 14, 2009, and FDA investigators advised Apotex that it should provide FDA with a proposal for the firm's next steps on Monday, August 17. The Parties planned to talk for one hour on that Monday at 3:00 p.m. However, before that call even took place, FDA had already started preparing the draft Import Alert request.

At 3:21 p.m., shortly after the scheduled hour-long telephone conversation took place,

Dr. Carmelo Rosa circulated his revisions to the draft Import Alert request. By 5:00 p.m. on the Monday, FDA internally circulated a draft of the Import Alert request that incorporated Dr. Rosa's comments.

The draft Import Alert request was cleared on Wednesday, August 19. The final version of the Import Alert request was prepared on August 20, and endorsed by CDER on August 24.

CDER sent its request to DIOP on Tuesday, August 25. By Friday, August 28, around noon, DIOP had approved the Import Alert.

This rushed time frame is contrary to FDA's general policy, according to which, FDA reviews a firm's response to a Form 483 before deciding to take enforcement action. This policy was acknowledged by Dr. Rosa in his Witness Statement. Yet, FDA imposed the Import Alert before Apotex had a chance to respond to the Form 483 issued at the end of the Signet inspection and before FDA had completed its review of Apotex's responses to the Etobicoke Warning Letter. On this record, FDA's adoption the Import Alert cannot be said to be impartial.

Second, FDA gave no notice to Apotex of the Import Alert. Apotex did not learn about the Import Alert until after it had already been imposed. FDA did not notify Apotex of the Import Alert; instead, Apotex found out about its existence during a conference call with Health Canada on September 2, 2009, after which Apotex confirmed that there was a posting on FDA's Web site about the Import Alert.

FDA told Apotex at the time that it was not required to notify Apotex of the Import Alert, as information was publicly available on FDA's Web site.

The U.S. does not dispute that it failed to notify Apotex of the Import Alert. It has proffered no evidence that it notified Apotex. In fact, the only evidence in the record, that of the testimony of Apotex Witnesses, shows that FDA never provided Apotex with notice of the Import Alert. Without notice, Apotex had no way to mount a defense.

The U.S. has argued that it should be excused from providing Apotex with notice because Apotex could have flooded the market. Nothing in the record, however, suggests that this was what motivated FDA at

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the time to adopt the Import Alert.

The U.S. does not deny that the record shows no FDA concern about flooding the market at the time. It does not suggest that there was any real risk of Apotex doing so. Rather, the U.S.'s argument on flooding the market is simply an exercise in ex post hypotheticals.

The U.S. contends that the Etobicoke Warning Letter and the verbal warning issued at the end of the Signet inspection were ample notice of FDA's intent to impose the Import Alert.

Apotex disputes that those things provided notice, but in any event, the Etobicoke Warning Letter was issued over two months before the Import Alert. Yet, Apotex did not flood the market during that time. Moreover, FDA is capable of monitoring import data and thereby preventing any flooding of the market.

In response to this argument, the U.S. simply noted that it reviews a large volume of data related to the importation of regulated products, but that FDA's system did not automatically flag sudden increases in imports in 2009.

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However, the U.S. offered no evidence to support this assertion. Nor is the U.S.'s implication that it might be difficult to monitor drug import activity due to its volume a persuasive reason to deny due process.

The evidence demonstrates that FDA's lack of notice to Apotex was not about any actual fears of flooding the market, but rather, reflected FDA's general policy not to give advance notice of an Import Alert to any firm.

Given the devastating effects of Import Alert, Apotex respectfully submits that a blanket denial of basic due process to an undifferentiated class of companies cannot be supported. International law requires that notice should be provided unless the circumstances justify urgent action. The approach of the international law, contrary to the U.S. suggestion, poses no challenge to States' power to take meaningful Measures to protect public health.

Here there is no evidence that any Apotex products shipped to the U.S. were actually contaminated or posed a risk to health and safety.

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FDA did not identify any known or suspected injuries caused by Apotex products in the Sharfstein Report, the weekly report that my colleagues mentioned earlier.

FDA drafted an information advisory for the Secretary of Health and Human Services that noted that there was no evidence that Apotex products were unsafe. This lack of evidence is further demonstrated by FDA's decision to classify Apotex's voluntary recall as Class II, which provides that the possibility of serious adverse health consequences is remote.

FDA never requested Apotex to recall any products or to expand the voluntary recall that Apotex had initiated. FDA's Expert, Mr. Vodra, suggests that FDA had no reason to believe that a formal request for a recall would change Apotex's intentions. However, Teva's experience suggests otherwise.

As noted by Mr. Johnson and Mr. Bradshaw in their First Report, FDA asked Teva to recall products that Teva had not volunteered to withdraw, which Teva did. This demonstrates that if expanding the scope of

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Apotex's recall was important to FDA, all it had to do was ask. But FDA did not.

Moreover, Mr. Vodra acknowledged that it was unnecessary for FDA to request any third-party testing of Apotex products or to seize Apotex products in Apotex-U.S.'s Indianapolis warehouse because Apotex had already volunteered to conduct third-party testing and promised not to distribute any further drugs in the U.S.

MR. LEGUM: Mr. President, we've been going for about an hour and a half. We've got a bit more to go. So it's up to the Tribunal, but this might be a good time to take a short break.

PRESIDENT VEEDER: Let's take a break for the shorthand writer at least. Let's say 15 minutes, and we'll come back 5 to 5:00. And then--again, we're not pressing you, just some idea of whether you'll finish today?

MR. LEGUM: I think, as I said before I think we can finish--

PRESIDENT VEEDER: You indicated you might finish today. Obviously, we're here tomorrow morning

as well.
MR. LEGUM: Yes.
PRESIDENT VEEDER: So we're on target.
MR. LEGUM: We are.
PRESIDENT VEEDER: Thank you. 15 minutes it is.
(Brief recess.)
PRESIDENT VEEDER: Let's resume.
MR. LEGUM: Just before turning the floor back over to Ms. Weil, a couple of quick points.
First, during the last presentation, we referred to Rick Friedman as the director of CDER. That's not accurate. He was the director of the Division of Manufacturing and Product Quality in the Office of Compliance of CDER. So two levels down from the director of CDER. So that's one correction.
And then the other is, I am told by Mr. Bradshaw that for people in the industry, the description that I gave of the generic drug scandal of the 1980s was incomplete in that what was truly shocking about it was that there were FDA officials that were being bribed by generic pharmaceutical

companies to take applications. And the big scandal was that a number of officials, as well as generic pharmaceutical company officers and directors, went to jail and hundreds of drugs were withdrawn from the market, and it really shook the faith of the public in the generic drug industry at that time.
So, with that amplification, I'll turn the floor back over to Ms. Weil.
MS. WEIL: Thank you.
Prior to the break, we discussed the first of the two pertinent Restatement factors. I've like to now move on to the third of those. That would be that FDA never detailed why it imposed the Import Alert. This prevented Apotex from mounting any defense or responding to FDA's position.
As a preliminary matter, I would like to address an odd assertion by the U.S. in its Rejoinder. The U.S. Rejoinder asserts that Apotex argued FDA's absence of reasons for the first time in the Reply. This assertion is impossible for us to understand. Apotex has argued that FDA did not give any reason for imposing the Import Alert since Day 1.

For example, Apotex's Request for Arbitration, which you see on the screen, which is dated February 29, 2012, states that "The FDA provided no notice to Apotex of its proposed action or its reasoning."
The Memorial also states that the United States failed to provide Apotex adequate information with respect to the nature of proceedings so as to permit the alien to present his claim or defense.
A few paragraphs later, Apotex stated that FDA never presented Apotex with reasons for its adoption of the Import Alert.
Perhaps the U.S. was in a hurry when it reviewed the request for--the Request for Arbitration and the Memorial and skipped over those parts. Otherwise, it is very difficult for us to understand how the U.S. could see this as a new position on Apotex's part.
Now that we've established that this is not a new argument, I'll turn to the evidence.
As you can see, beyond a general reference to drug GMPs, the Import Alert itself and detention

notices given to importers do not describe the reasons for an Import Alert. Instead, FDA set out its rationale for the Import Alert in an FDA internal memorandum that was never given or communicated in substance to Apotex. Apotex's counsel obtained this memorandum years later and only through a FOIA request. Apotex was never told the reasons for the Import Alert and certainly had no notice and no information at the time that would permit it to present a claim or defense.
The U.S. argues that the reasons for the Import Alert were contained in Forms 483, EIRs, the Etobicoke Warning Letter, and calls and meetings that it had with Apotex. This argument is flawed for several reasons. Forms 483, such as the one that you see on the screen, expressly state that they are not findings, and thus, they cannot inform Apotex of the reasons for the Import Alert. Moreover, companies have the opportunity to respond and explain the observations listed on a Form 483 and may thus resolve any concerns before an Import Alert would be issued.
Likewise, Warning Letters do not

17:00:09 provide--excuse me--do not explain why FDA did or did not adopt an Import Alert. As noted at some length in the discussion of national and MFN treatment, many companies receive Warning Letters without any enforcement action being taken. That a company receives a Warning Letter does not mean that it will be put on Import Alert.

Moreover, with respect to the Etobicoke Warning Letter, Apotex responded to each issue raised by FDA, and FDA eventually accepted Apotex's explanations. Unfortunately, FDA did not review Apotex's response until after the Import Alert was issued. Nor could the Signet Warning Letter provide reasons for the Import Alert because the Import Alert was issued seven months before Apotex received the Signet Warning Letter. And so the Import Alert obviously cannot be based upon that document.

With respect to the Establishment Inspection Reports, or EIRs, the record does not support the Rejoinder's assertion that FDA provided them to Apotex. In fact, the first time that Apotex saw the EIRs for Etobicoke and Signet was when the U.S.

17:01:21 included them as exhibits to its Counter-Memorial in this arbitration. Nor can the meetings or telephone calls with FDA truly explain FDA's justification for the Import Alert, as these conversations were principally focused on Apotex's efforts to enhance its systems further to address FDA's concerns. Not only were these conversations substantially forward-looking rather than backward-looking, even to the extent that they discussed those concerns, the discussion did not purport to explain why the Import Alert had been imposed.

In addition to pointing to Forms 483, EIRs, the Etobicoke Warning Letter, and calls and meetings with Apotex, the U.S. points in its Rejoinder to publicly available information, such as--and I quote the Rejoinder at Paragraph 38--"statutes, regulations, procedural manuals, forms, frequently asked questions, Warning Letters, and Import Alerts"...

However, these general policy materials hardly substitute for informing Apotex of the specific reasons why its products were prevented from reaching Apotex-U.S. and the U.S. market. FDA intentionally

17:02:36 drafted its cGMP regulations in very general and flexible terms in order to allow each manufacturer to decide individually how to best implement the necessary controls.

Contrary to what the U.S. argues, these GMP regulations do not provide objective standards for decision makers. Moreover, Mr. Vodra testified that, to his knowledge, FDA hadn't reduced to writing "how its officials are to weigh and integrate these various factors to reach a final judgment as to whether to initiate enforcement actions."

Thus, the suggestion that Apotex knew exactly why the Import Alert was imposed because of publicly available information is without merit. On this record, it is clear that FDA failed to inform Apotex of its reasons for imposing the Import Alert.

I now turn back to my colleague, Mr. Legum, who will discuss how none of the U.S. remedies were available or effective in providing Apotex with any due process after the Import Alert was adopted.

MR. LEGUM: Thank you.

Because the U.S. never provided notice of the

17:03:56 Import Alert or any opportunity to present views before it was adopted, the only means for the U.S. to satisfy its obligations under the minimum standard would be to provide due process after the fact. However, the U.S. also failed to provide any meaningful route for Apotex to obtain due process after the adoption of the measure.

The U.S. suggested four avenues were available to Apotex: Reconsideration, citizen petition, detention hearings, or suit in court under the Administrative Procedure Act. But none of these would have provided Apotex with the available and effective relief required by international law.

Now, the U.S. does not suggest that FDA ever advised Apotex of any of these four purportedly ubiquitous avenues during any of the calls or meetings Apotex had with FDA. FDA did not.

Instead, FDA's position, both to Apotex and internally, was that successful re-inspection was the only way Apotex could remove the Import Alert.

As the August 20, 2009, memorandum from CDER to DIOP requesting the Import Alert noted, FDA's

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position was "if and when the firm can demonstrate that it is in compliance with cGMPs and a re-inspection confirms that appropriate corrections have been implemented, CDER will request removal of the firm from Import Alert for Detention Without Physical Examination."

On September 3, 2009, FDA told--FDA told Apotex that a successful re-inspection was the only way to lift the Import Alert, and that appeal to the district officer at a detention hearing would, at best, address shipments on a case-by-case basis.

The minutes state that "Apotex asked about what would need to occur for the Import Alert to be lifted. FDA responded that the issues identified in the reports issued would need to be corrected and that the corrections would need to be verified by a re-inspection by FDA."

FDA reiterated this message in a meeting on September 11, 2009. You see the language on the screen.

At that meeting FDA said that it would require re-inspection and they will re-inspect when

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they have assurance that cGMP conformance has been instituted and that all deficiencies have been resolved. During that same meeting, as you can see on the slide, Mr. Rivera-Martinez also said that the Commissioner had made it very clear that a re-inspection would be necessary to close out actions of this kind.

As noted in a September 14, 2009, statement to the public, Apotex stated its understanding based on FDA's repeated statements to it: "Until such time that the facilities are re-inspected, the Import Alert will not be lifted."

This accords with the FDA Regulatory Procedures Manual, which states that analysis of samples is generally insufficient to remove an Import Alert and that re-inspection may be required.

As Apotex noted in its Reply, it appropriately relied on FDA's statements that the Import Alert could be lifted only upon successful re-inspection.

And I refer to the Tribunal to the Reply at Paragraph 467.

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In its Rejoinder, the U.S. did not dispute that FDA's unchanging position at the time was that re-inspection was required to lift the Import Alert. The U.S. also did not dispute that under international law, as noted by the International Court of Justice in the Diallo case, a Claimant is "justified in relying on the consequences of the legal characterization thus given by the executive authorities, including for purposes of the local remedies rule."

Thus as a matter of law, Apotex was entitled to rely on FDA statements that re-inspection was the only way to lift the Import Alert.

Now, if the four avenues proposed by the U.S. now were so available and effective, it defies understanding that no one suggested them to Apotex before this arbitration. Taken together, the record does not support the U.S.'s assertion that numerous effective remedies were available to Apotex at the time.

As the Loewen Tribunal recognized, remedies must be effective, adequate, and reasonably available to the complainant in order to meet the minimum

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standard of treatment. Under international law, the U.S. bears the burden of proving its assertion that these remedies existed, would have been effective, and were not exhausted. This principle is recognized by numerous tribunals such as ELSI, Diallo, Ambatielos, and Chevron. Quotes from the relevant cases appear on the screen. But this is precisely what the U.S. did not do.

The U.S. disputes in its Rejoinder that it bears the burden of proving that U.S. law could have provided Apotex the relief that it sought. Relying on the Apotex I and II Case, the U.S. suggests that the burden of proof relies on Apotex to demonstrate the "obvious futility" of any domestic remedies. I refer here to the Rejoinder at Paragraph 321.

However, the U.S.'s reliance on the Apotex I and II case is misplaced here because that case arose in the context of a claim for a substantive denial of justice by an independent court. In such a context, justice is not denied if justice remains to be pursued. There, local remedies are a substantive part of the claim, not a procedural defense. In contrast,

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here, denial of justice by an independent court is not at issue, and the burden falls on the U.S. to prove its assertions that the four avenues were available and adequate.

The U.S. has failed to do so, and I will now turn to each one of the four proposed avenues in turn.

PRESIDENT VEEDER: Just before you do that, you've very helpfully listed the relevant cases on your slide, Number 54. Is there anything that we need to understand about the other Apotex Award? Was this an issue?

MR. LEGUM: My recollection is that it was presented in that case, and as I said, the Tribunal did find that the burden did not lie on the Respondent in the context of that case.

That case, however, differs from this one in that it involved a claim of a substantive denial of justice by an independent court. And in that context, as the Loewen Tribunal recognized, that claim may not be made out if there were effective and adequate remedies available to be exhausted. The reason being that the nature of the claim of denial of justice is

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that the State has failed to provide a system of justice that, on the whole, is adequate under international law.

And if there is an appeal from a court decision that would otherwise violate the international minimum standard, as was the case in Loewen, then that would defeat a claim that the State has failed to provide an adequate system of justice. We would submit that that case does not apply in this context because there is no claim here of a denial of justice by an independent court. So I begin with reconsideration under 21 CFR Section 10.75.

This is not an effective remedy because it is discretionary, does not provide the opportunity to vindicate a right, and relies on the grace of the very same office that imposed the Import Alert. Moreover, it does not provide any ability to present new evidence or witnesses.

Section 10.75 allows a decision by an FDA employee to be reviewed by that employee's supervisor based on the record used originally. The reconsideration request does not meet customary

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international law standards of due process because it is not decided by an impartial Party.

Any request for reconsideration would be made to CDER, the same office that requested the Import Alert. Reconsideration also would not permit Apotex to defend itself or to contest evidence against itself because it is decided on the basis of the record of the original decision, a record to which Apotex had no access and to which it did not contribute.

Mr. Rowley.

ARBITRATOR ROWLEY: Am I correct that the record indicates that no request for reconsideration was made or sought by Apotex?

MR. LEGUM: That is correct.

ARBITRATOR ROWLEY: And does the record indicate why?

MR. LEGUM: The record does not indicate why. My understanding is that this was never identified as anything that was available to Apotex to do.

ARBITRATOR ROWLEY: Well, I suppose it doesn't matter. If it existed, it depends on whether one looks at the law. But the question--I don't want

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to prejudge that issue. The question I had was, was it pursued? The answer is no. And there's no evidence as to why it was not pursued. That's as I understand the nub of the answer.

MR. LEGUM: I may return to this tomorrow morning after I've had a chance to review the record more. I'm being reminded by a colleague that there may be some evidence on the record on this.

ARBITRATOR ROWLEY: Well, I probably have the same question about each of the remedies you're going to deal with. So you can deal with that all at one time.

MR. LEGUM: Certainly.

As the Diallo Tribunal noted, executive reconsideration of a decision does not constitute a remedy under international law when it is aimed at obtaining a favor rather than vindicating a right. This principle has been upheld by the International Court of Justice, the International Law Commission, and many other sources of international law. A reconsideration request is a discretionary one that does not depend on any principles or standards.

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17:16:36 MR. SHARPE: I'm sorry, Mr. President. If I might just note that two of the sources that were cited on the last slide, as we understood, had been withdrawn by Claimants on the first day. So we would just note that for the benefit of the Tribunal.

Thank you.

CLA-637 and CLA-638 we had understood were withdrawn.

MR. LEGUM: That's absolutely correct. We did not correct this slide. And what we'll do is we will provide tomorrow morning a replacement slide for members of the Tribunal.

PRESIDENT VEEDER: Slide 56, we just cross out CLA-637, Hartman; CLA-638, Horvat.

MR. LEGUM: That's right. And don't read them.

PRESIDENT VEEDER: Well, too late.

MR. LEGUM: My apologies for that.

PRESIDENT VEEDER: Thank you for that.

MR. SHARPE: Thank you.

MR. LEGUM: However, let's do look at the language at the top case, which is on the record,

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17:17:34 which is the Diallo case. And in this case, the Court recalled that while the local remedies rule that must be exhausted includes all remedies of a legal nature, judicial redress, as well as redress before administrative bodies, administrative remedies can only be taken into consideration for purposes of the local remedies rule if they are aimed at vindicating a right and not obtaining a favor.

Now, although the U.S. suggests in its Rejoinder that this form of review constitutes an appeal because the decision is reviewed by someone with higher authority--this is at the Rejoinder in Paragraph 346--this argument does not withstand scrutiny. The evidence indicates that various individuals--such as the director of CDER's Office of Compliance, Deborah Autor, CDER's Director, Janet Woodcock--themselves participated in the decision to impose the Import Alert.

The U.S. does not identify to whom this supposed appeal would lie. And in any event, the authority making the decision remains the same agency. Reconsideration is not an effective remedy under

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17:19:00 settled international law and the record in this case.

The second remedy proposed by the U.S. administratively challenging FDA's cGMP findings by filing a citizen petition under 21 CFR Sections 10.25 and 10.30 is not an effective remedy because it is a discretionary proceeding that does not apply or require due process safeguards.

A citizen's petition allows someone to ask that the Commissioner take or refrain from taking a specific administrative action. Petitions are publicly posted, and interested Parties may submit written comments. After evaluating the petition, FDA decides to grant or deny the petition. This evaluation process can take more than a year.

This avenue does not provide the due process safeguards required by international law because it is a discretionary act on the part of FDA that has no principles or standards governing the grant or denial of the petition.

FDA is permitted to take to issue tentative responses rather than final binding ones. The petition does not include the right to a hearing or

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17:20:28 obligate FDA to investigate or to act. In the petition procedure, the Petitioner has no right to review information held by FDA relating to the issue or to rebut any of that information as part of its defense.

Now, although the U.S. has argued that a citizen petition would have allowed Apotex to take any objections to FDA decisions directly to the FDA Commissioner--I refer to the Rejoinder at Paragraph 353--the U.S. fails to recognize that the Commissioner has delegated the authority to issue decisions on citizen petitions right back to CDER, the very office that made the original determination. And I refer here to FDA Staff Manual Guides at Page 3, Section 1(h). The exhibit reference is R-184.

Now, as FDA has acknowledged, in many instances--and the language is on the screen--it is readily apparent that citizen petitions may not be the best or most efficient mechanism for addressing the underlying subject or issue. In contrast, a telephone call, letter, or request for a meeting, while lacking the formal processing associated with citizen

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17:21:54 petitions, is usually an easier, fairer, and more efficient way to discuss the same issue with the agency.

The U.S.'s Witness--or Expert, Mr. Vodra, confirms that in his experience "the citizen petition can be a cumbersome pathway" and that "formal agency action can be delayed." This is Paragraph 103 of the Vodra Expert Report.

The U.S. has provided no evidence that citizen petitions are an adequate or effective way to challenge an Import Alert. Indeed, the U.S. has provided no evidence that any Import Alert has ever been successfully challenged via a citizen petition, nor did Mr. Vodra testify that a citizen petition would be effective. Instead, he tepidly suggested that he "cannot presume a fortiori that a citizen petition is never useful to provide prompt and effective relief." That's Paragraph 103 of the Vodra Expert Report.

Even setting aside these obvious problems, the U.S. fails to explain how Apotex could have used the citizen petition process to challenge the Import

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17:23:19 Alert when FDA never told Apotex the basis for its decision to impose the Import Alert, and the citizen petition process does not provide a petitioner with the right to review FDA information.

Without reviewing FDA's rationale for the Import Alert, Apotex could not have effectively challenged it. Apotex did not file a citizen petition, to answer Mr. Rowley's question.

The third proposed remedy, a post-detention hearing, could not have been effective because it permits a challenge to the detention of a specific shipment rather than a ban on importation generally. Moreover, the detention hearing would not be before--would be before a district director who had no power to lift the Import Alert. Instead, the center, CDER, had sole authority to lift the Import Alert.

Although the U.S. claims in its Rejoinder that Apotex declined FDA's express invitation to provide oral or written testimony for a detention hearing--I'm referring to Paragraph 325--the U.S. does not dispute that the district director lacks authority to lift the Import Alert. Thus, the U.S. concedes

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17:24:50 that a post-detention hearing would be ineffective and a futile exercise.

Instead, in its Rejoinder, the U.S. presented a revised argument that Apotex should have combined two of the three remedies proposed by the U.S. by appearing at the admittedly ineffective detention hearing and then appealing the post-detention hearing decision to the decision maker's supervisor. This is what appears in Paragraph 343 of the Rejoinder.

But the U.S. argument that Apotex could have appealed the decision of a post-detention hearing is at odds with the record.

First, the Regulatory Procedures Manual advises hearing officers not to be forthcoming about avenues of appeal. The RPM provides that "If the question arises, the Respondent should be made aware of their rights of appeal to a higher level of review in the agency," but it does not require hearing officers to apprise a Party of such an appeal. I'm referring here to CLA-309 at Page 35.

FDA told Apotex that appeal to the district officer at a detention hearing would, at best, address

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17:26:15 shipments on a case-by-case basis. "But this would require data showing that the issue resulting in the Import Alert had been addressed." That language appeared on the screen and is in your books at Slide 59--excuse me, Slide 60.

The same meeting minutes make unmistakably clear that only a re-inspection could result in the Import Alert being lifted. These minutes reflect that FDA did not say that a detention hearing was a method by which Apotex could lift the Import Alert.

Likewise, meeting minutes from September 11, 2009, also failed to mention detention hearings as being an effective way to challenge the Import Alert and reiterate the necessity of re-inspection.

Finally, the U.S.'s suggestion in its Rejoinder that Apotex "could have attempted to ship production to the United States and invoked its right to a hearing when the products were detained to establish their admissibility" is difficult to understand. The reference I just made was to Rejoinder Paragraph 344.

The U.S., in its defense of Apotex versus the

17:27:42 comparators, places great emphasis on the importance of drug companies being perceived to cooperate with FDA.

Now it suggests that it would have been in Apotex's interest to flout FDA's Import Alert and attempt to ship products to the U.S. despite FDA's official position to the contrary.

The U.S. position is irreconcilable, as well as being inconsistent with the concern the U.S. now raises, but did not at the time, that Apotex would attempt to flood the market with products.

PRESIDENT VEEDER: Is that a fair criticism? I'm just reading Paragraph 344, because it assumes that Apotex would have come into compliance. So I'm not sure it would be quite as blatantly flouting, as you might suggest.

MR. LEGUM: Allow me to catch up with you, if you don't mind.

PRESIDENT VEEDER: Paragraph 344, Page 176.

MR. LEGUM: I think that your reading of that provision is correct--that statement is correct. But I would note that coming into compliance, as FDA

17:29:18 repeatedly made clear to Apotex, required a re-inspection.

So the point really comes to the same. If the only way for Apotex to be deemed to have come into compliance was to be re-inspected, there was no effective means of challenging the Import Alert other than going through the re-inspection process and being found to be in compliance.

I come to the last remedy proposed by the U.S.: Bringing suit under the Administrative Procedures Act. This also was not an effective remedy because U.S. courts do not have jurisdiction to review discretionary and nonfinal acts like the Import Alert.

In its Counter-Memorial, the U.S. suggested that Apotex said one thing in U.S. courts and told this Tribunal another. That suggestion was baseless as concerns Apotex. Its inverse, however, comes to mind in considering the U.S. position on the Administrative Procedure Act's application to Import Alerts.

In its Rejoinder, the U.S. asserts before this Tribunal that Apotex had available to it the

17:30:40 possibility of seeking judicial review of an Import Alert. But the consistent position of the U.S. in U.S. courts has been that no judicial review of Import Alerts is possible.

In at least two cases, notably, KV Pharmaceutical Company versus FDA and Smoking Everywhere versus FDA, CLA-542 and CLA-1438, FDA has argued that an Import Alert is a discretionary act not reviewable by the U.S. courts. The U.S. acknowledges, in its Rejoinder, that the Executive Branch takes the position in U.S. courts that Import Alerts cannot be challenged under the APA because such decisions are committed to FDA discretion.

ARBITRATOR ROWLEY: Can you tell us what the courts say in response to the position of the U.S. Respondent in those proceedings?

MR. LEGUM: So far as I'm aware, there is not a court that has upheld its jurisdiction to review an Import Alert. But I'd like to check that with the Experts before committing to it.

The U.S. even acknowledges in its Rejoinder that the Executive Branch takes the position in U.S.

17:32:09 courts that Import Alerts cannot be challenged under the APA before such decisions are committed to FDA discretion. That's a reference to Paragraph 364 of the Rejoinder.

Yet in this arbitration, the U.S. still suggests that Apotex could have attempted to challenge the Import Alert by filing suit under the APA. The U.S.'s suggestion that Apotex initiate a lawsuit that the U.S. would immediately move to dismiss on jurisdictional grounds is not serious.

The U.S. further tries to muddy the waters by pointing to "two courts that have allowed claims challenging certain other aspects of FDA's implementation of the relevant section of the Food, Drug, and Cosmetic Act." This is the Rejoinder at Paragraph 364 that I'm referring to.

The cases that the U.S. refers to are Smoking Everywhere and Cook versus FDA.

Well, first, both of these cases were decided after--both of these cases were decided after Apotex was put on Import Alert, and so they did not reflect the state of the law at that time. More importantly,

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17:33:34 these challenges were not to an Import Alert, but to other aspects of FDA action.

Smoking Everywhere challenged FDA's regulatory authority under the Food, Drug, and Cosmetic Act to regulate tobacco products generally and whether a particular product was even a drug subject to the Food, Drug, and Cosmetic Act. It said nothing about whether a court has jurisdiction to hear a challenge to the FDA's decision to issue an Import Alert.

Cook addressed whether FDA's decision to allow imports--well, whether FDA's decision not to ban but to allow imports of certain deadly products that violated the Act was entitled to deference.

Neither addressed Import Alerts as such. Judicial review of the Import Alert is not an available remedy under international law.

I would conclude on this particular point by noting that nothing in the record--there is no evidence in the record, despite Expert Reports submitted by both Parties, of any instance in which any Party has successfully used any of the four

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17:34:58 proposed methods of review that the U.S. identifies successfully to challenge an Import Alert based on cGMP observations.

I would now like to turn to the U.S.-Jamaica Bilateral Investment Treaty.

The substantive provisions that Treaty apply by virtue of the NAFTA Article 1103. The U.S. did not dispute this in its Counter-Memorial. In other words, it did not dispute that substantive provisions may be attracted by virtue of the Most-Favored-Nation Clause found in Article 1103 or that treatment provided to foreign investors under post-NAFTA Bilateral Investment Treaties constitutes treatment under Article 1103.

Such a contention would be difficult, given the clear text of Annex 4 to the NAFTA, which contemplates international agreements signed and entering into force after the NAFTA applying under the Most-Favored-Nation Clause in Article 1103.

However, the U.S. did assert in its Rejoinder that Apotex did not identify a comparator in like circumstances as required by Article 1103. To the

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17:36:35 extent that the U.S. is claiming that Apotex was required to identify a specific Jamaican generic manufacturer or Jamaican entity with investments in the U.S. in order to avail itself of the U.S.-Jamaica BIT, the U.S. provides no support for such a requirement. There is no such requirement.

As the United Nations Conference on Trade and Development noted: "The comparison test has, in practice, worked differently depending on what Claimants were seeking from the MFN Clause. When Claimants were seeking better treatment, whether material or effective, such as in the cases referred to above, Tribunals have compared treatment amongst two foreign investors who are in identical circumstances. But when Claimants have invoked the MFN Treatment Clause in order to attract the benefits of ISDS, Investor-State Dispute Settlement, or substantive protection provisions from Third Treaties, Tribunals have been satisfied with the mere fact that the Claimant qualifies as an investor under the basic Treaty and have not gone into actually comparing the investor with another foreign investor from a third

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17:38:01 country."

Returning to what the U.S.-Jamaica Bilateral Investment Treaty actually does provide, the Treaty provides more favorable treatment than NAFTA Article 1105. The relevant provision is on the screen. It is Article 26 of the Jamaica-U.S. BIT--excuse me, yeah, Jamaica-U.S. BIT. Rather than setting out a standard defined by reference to customary international law, this Treaty sets out an independent obligation to provide effective means for asserting claims and enforcing rights. The Treaty text does not distinguish between the means required for administrative adjudication versus administrative decision making. Effective means of asserting claims is not limited in the BIT to adjudication only; thus, it may apply to administrative proceedings as well.

In the Rejoinder, the U.S. appeared to suggest that this BIT requires a State to provide effective means only if a Party can "assert claims or enforce rights in an effective adjudicatory forum."

I'm referring here to the Rejoinder Paragraph 373. This interpretation would thus limit

the rights served to those enforced in accord. This is, of course, nonsensical as rights exist outside of courts. Moreover, if the Treaty Parties intended to restrict the effective means to judicial remedies, they would have said so as has been done in other Bilateral Investment Treaties. At the Chevron versus Ecuador Tribunal held, the effective means standard is lex specialis which is different from and less demanding than the denial of justice standard under customary international law.

Apotex has amply demonstrated that it was not afforded an effective means to assert its claims or enforce its rights in relation to its investments because Apotex had no way to challenge the Import Alert. As discussed earlier, the four avenues the U.S. suggested did not constitute effective means for challenging the Import Alert.

Thus, in conclusion, the U.S. breached NAFTA Article 1105 and provisions of the U.S.-Jamaica BIT when it adopted the Import Alert without providing any of the due process standards enumerated in the Restatement and without providing effective means for

Apotex to enforce its rights.

This brings the Claimant to the close of its presentation to Article 1105(1). I would, of course, be happy to entertain any questions the Tribunal might have at this time.

PRESIDENT VEEDER: We have no questions at this time. Thank you very much, indeed.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: So we've come to the of are your submissions for today, but we'll start again at 9:00 for the further additions that you mentioned earlier.

MR. LEGUM: Yes. I anticipate that that will not take up an entire session, probably less than half. "Session" meaning from 9:00 a.m. to the 10:45 a.m. coffee break.

PRESIDENT VEEDER: Then we'll start with the Respondent's case. We're just starting a bit earlier. Thank you very much. We'll see you all at 9:00 tomorrow.

(Whereupon, at 5:42 p.m., the hearing was adjourned until 9:00 a.m. the following day.)

CERTIFICATE OF REPORTER

I, Dawn K. Larson, MBA-RDR, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

_____

DAWN K. LARSON